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Schultz

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(54) **CONTROL HANDLE WITH ROTATIONAL CAM MECHANISM FOR CONTRACTION/DEFLECTION OF MEDICAL DEVICE**

(71) Applicant: **BIOSENSE WEBSTER, INC.**, Diamond Bar, CA (US)

(72) Inventor: **Jeffrey W. Schultz**, Chino, CA (US)

(73) Assignee: **Biosense Webster, Inc.**, Diamond Bar, CA (US)

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Related U.S. Application Data

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A61M 25/01 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**

CPC ***A61M 25/0147*** (2013.01); ***A61M 25/0136*** (2013.01); *A61B 5/6852* (2013.01);
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See application file for complete search history.

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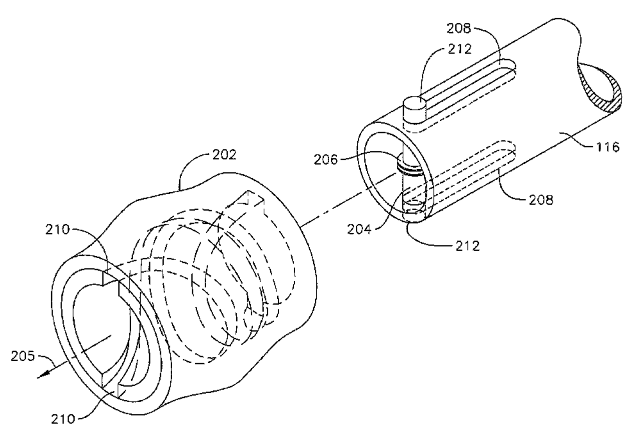
Primary Examiner — Theodore Stigell
(74) *Attorney, Agent, or Firm* — Christie, Parker & Hale, LLP

(57) **ABSTRACT**

A medical device has a distal member with a configuration that can be changed by means of a control handle with a control assembly employing a rotational cam, a shaft, and a pulley, where the rotational cam is rotationally mounted on a portion of the control handle for rotation by a user. The rotational cam operates on the shaft to move it proximally or distally depending on the direction of rotation which in turn rotates the pulley to draw or release a puller wire to change the configuration of the distal member of the medical device. The shaft is oriented along a diameter of the control handle. The shaft has two ends which extends through two axial guide slots in the portion of the control handle to sit two opposing helical tracks formed on inner surface of the rotational cam. The guide slots are parallel with the longitudinal axis of the control handle and therefore maintain the shaft's diametrical orientation as the rotational cam is rotated to move the shaft proximally or distally. Actuation of the puller wire by means of the control assembly can result in a change of the distal member's configuration, including deflection, contraction and/or expansion.

10 Claims, 21 Drawing Sheets



(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 17/00 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.**
CPC *A61B18/1492* (2013.01); *A61B 2017/003* (2013.01); *A61M 25/0052* (2013.01); *A61M 2025/015* (2013.01)

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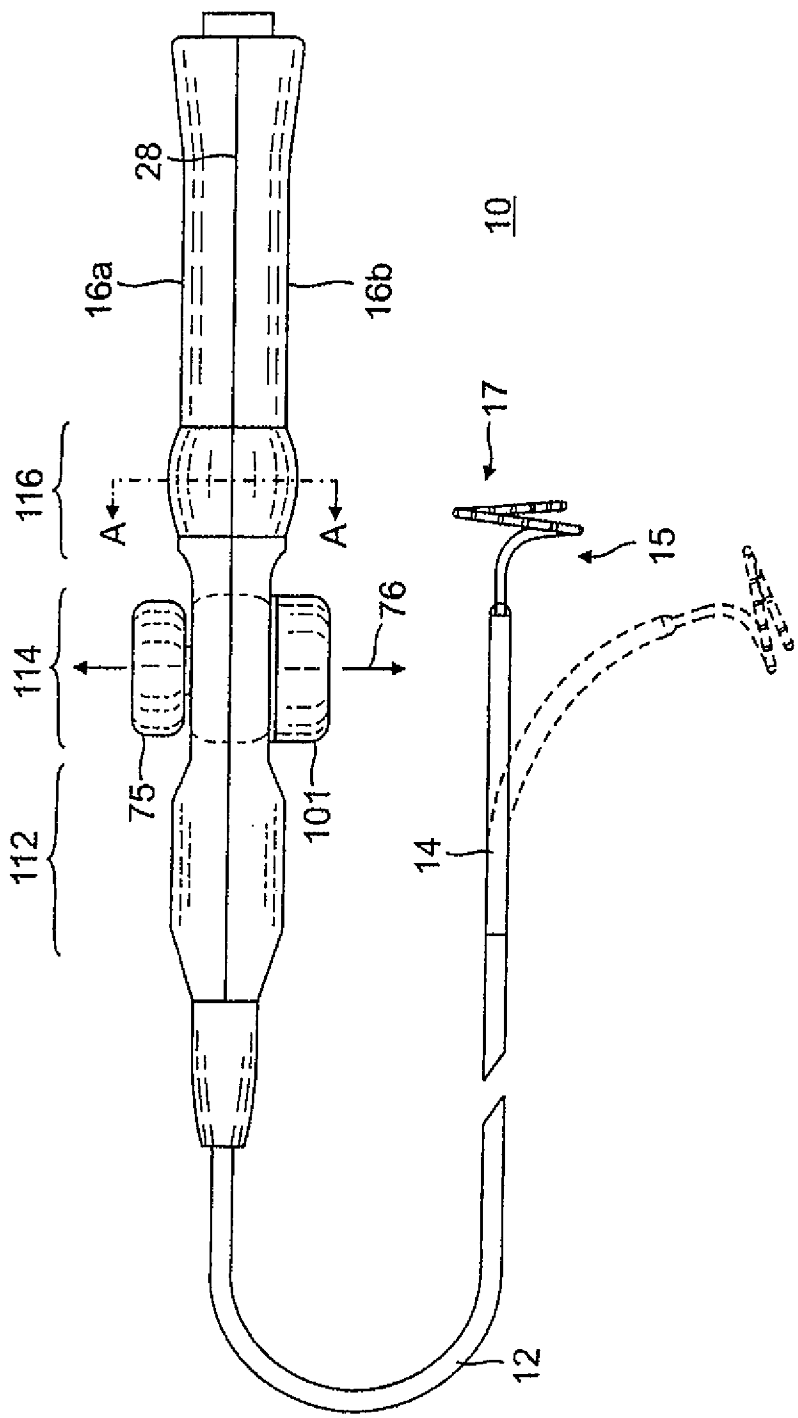

FIG. 1

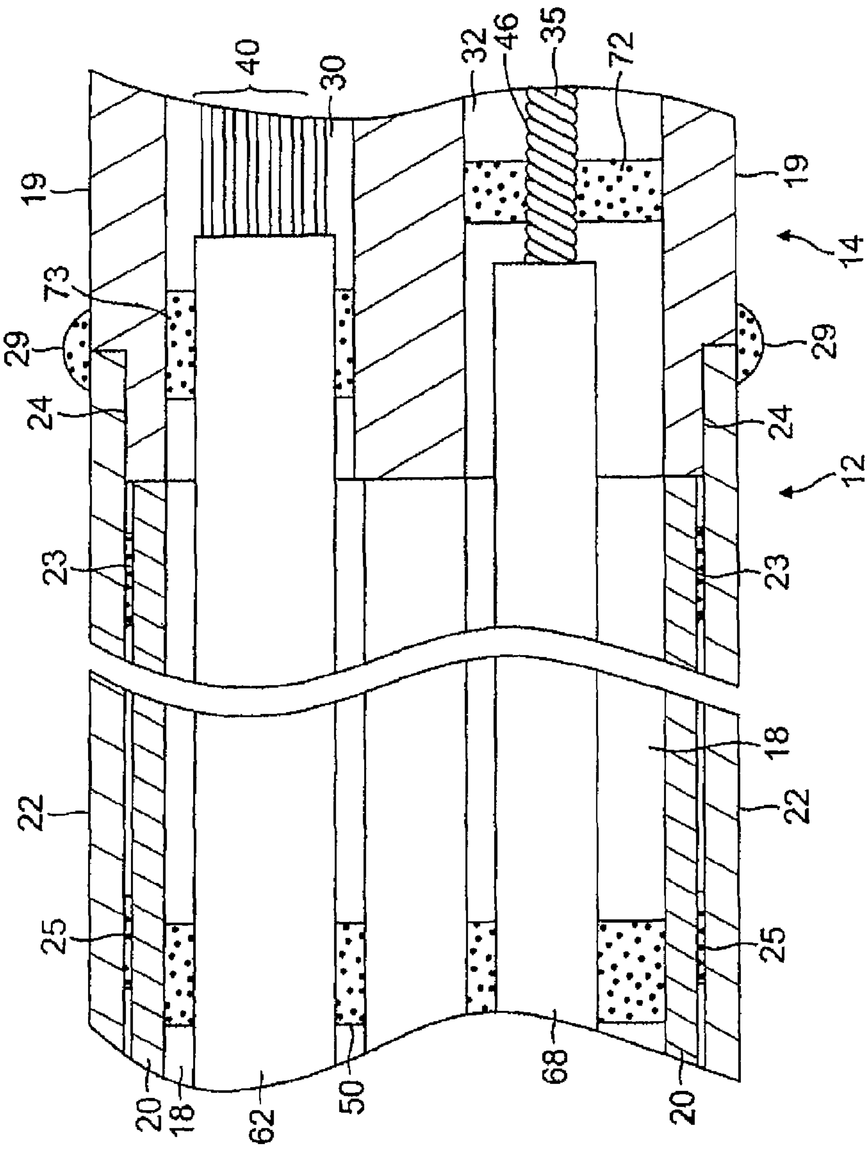
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FIG. 2A

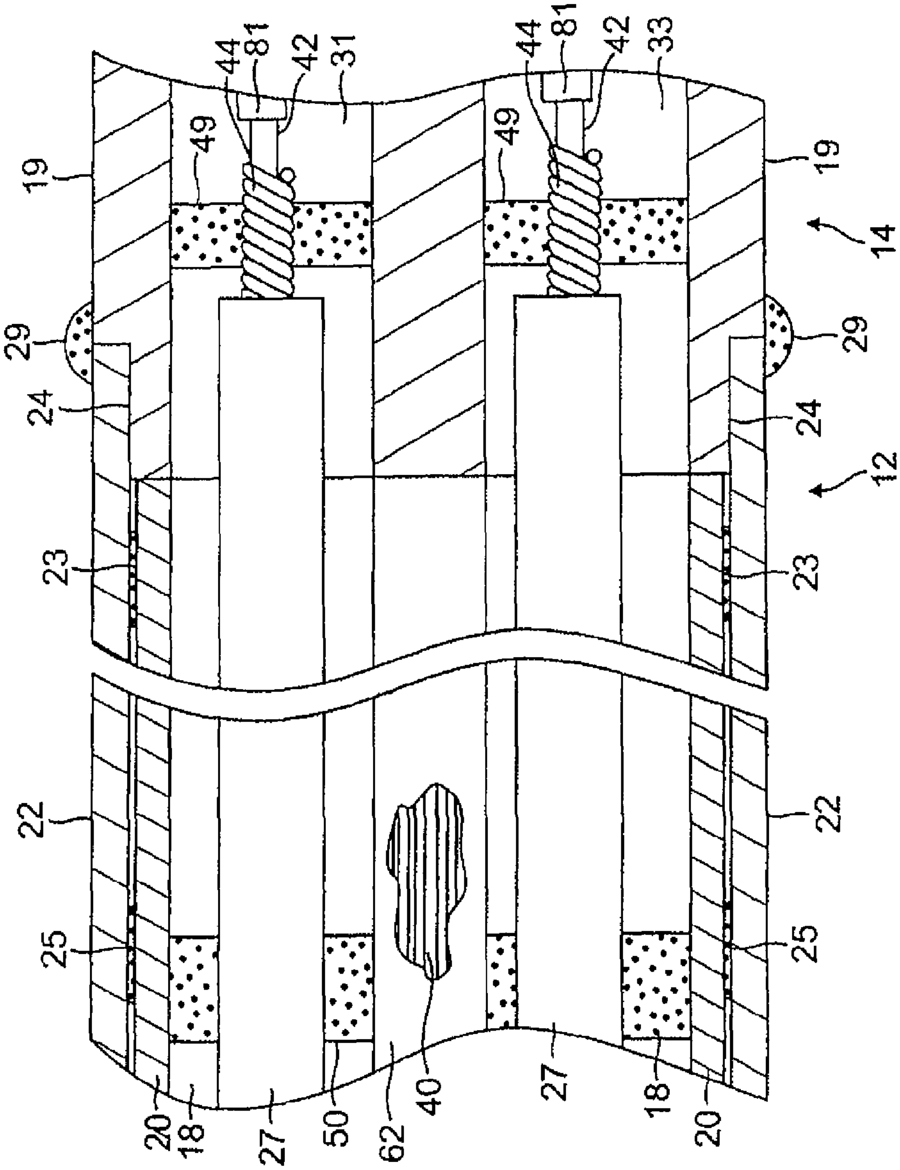

FIG. 2B

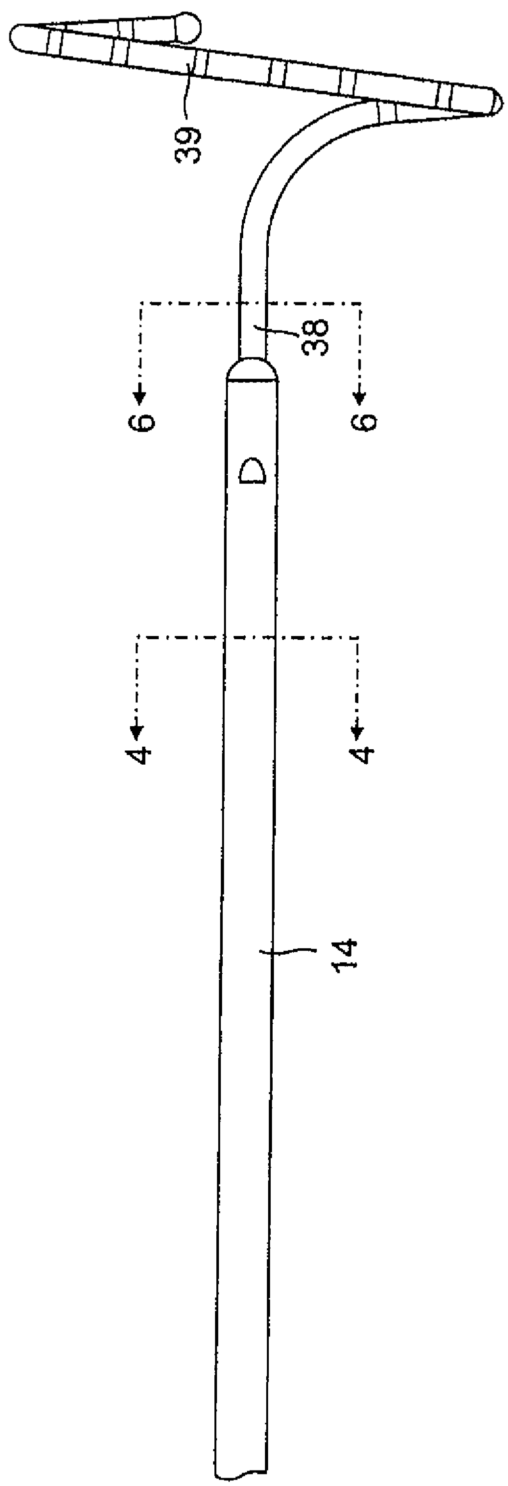

FIG. 3

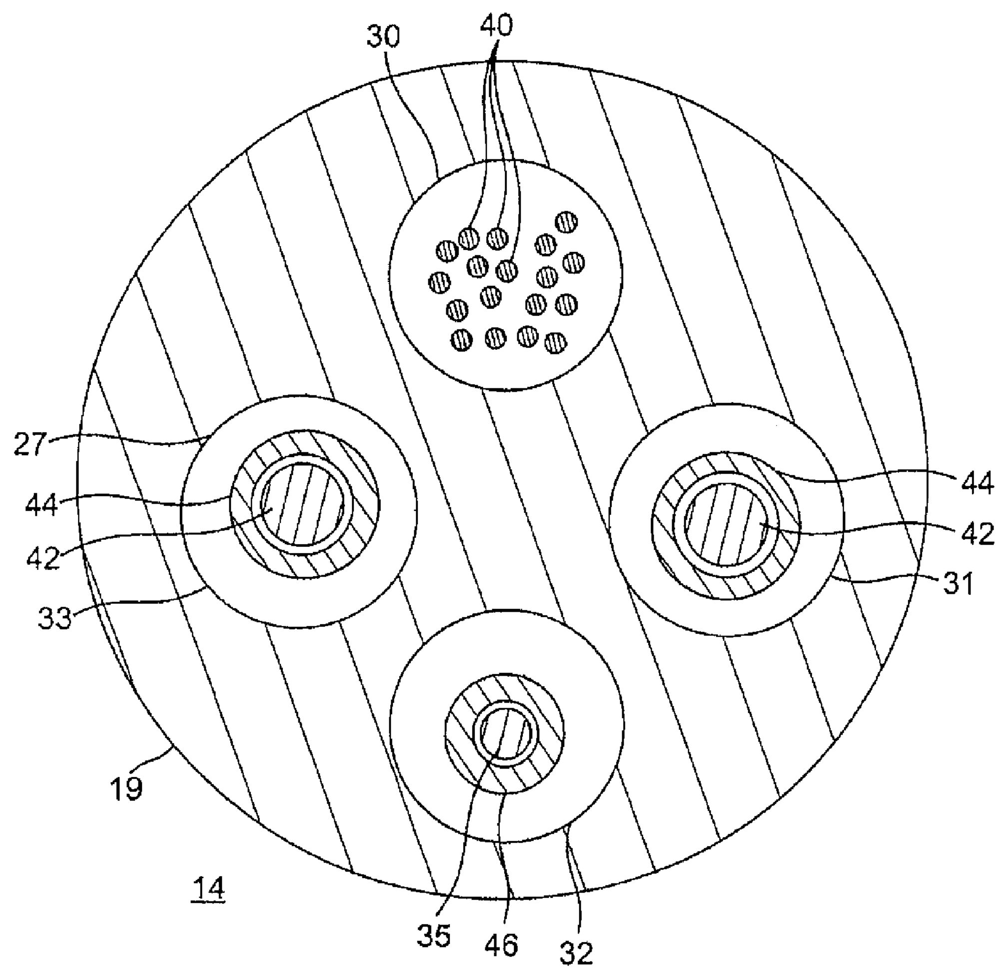

FIG. 4

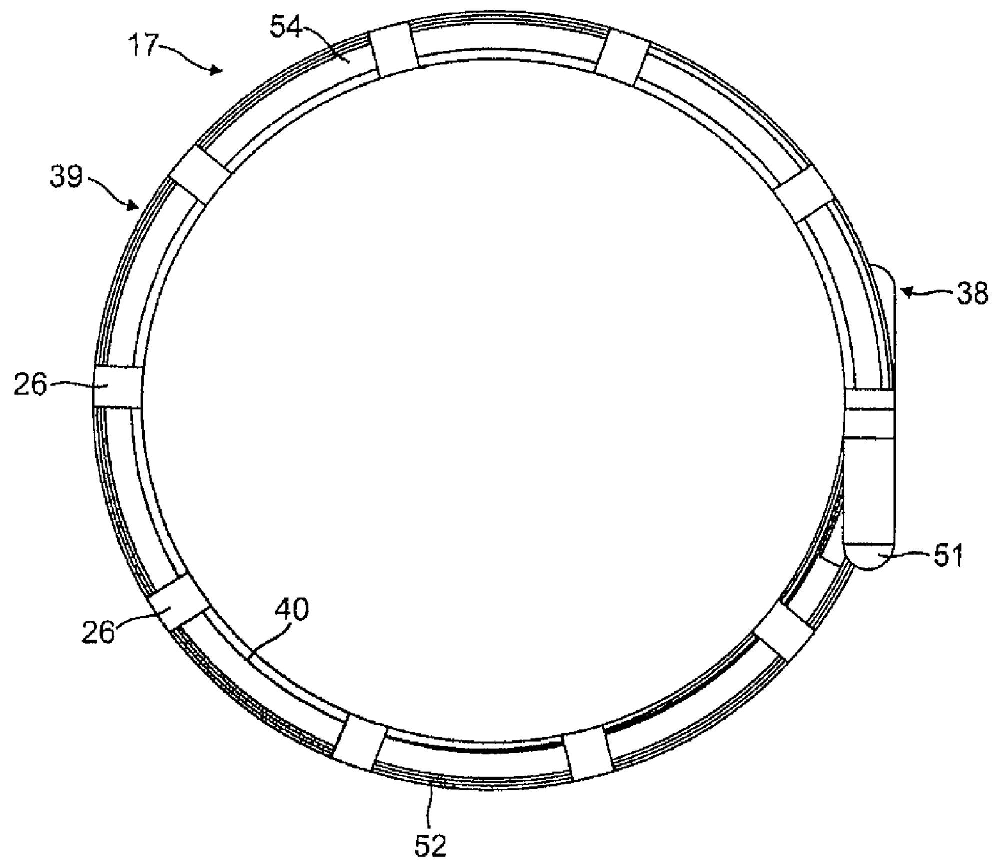

FIG. 5

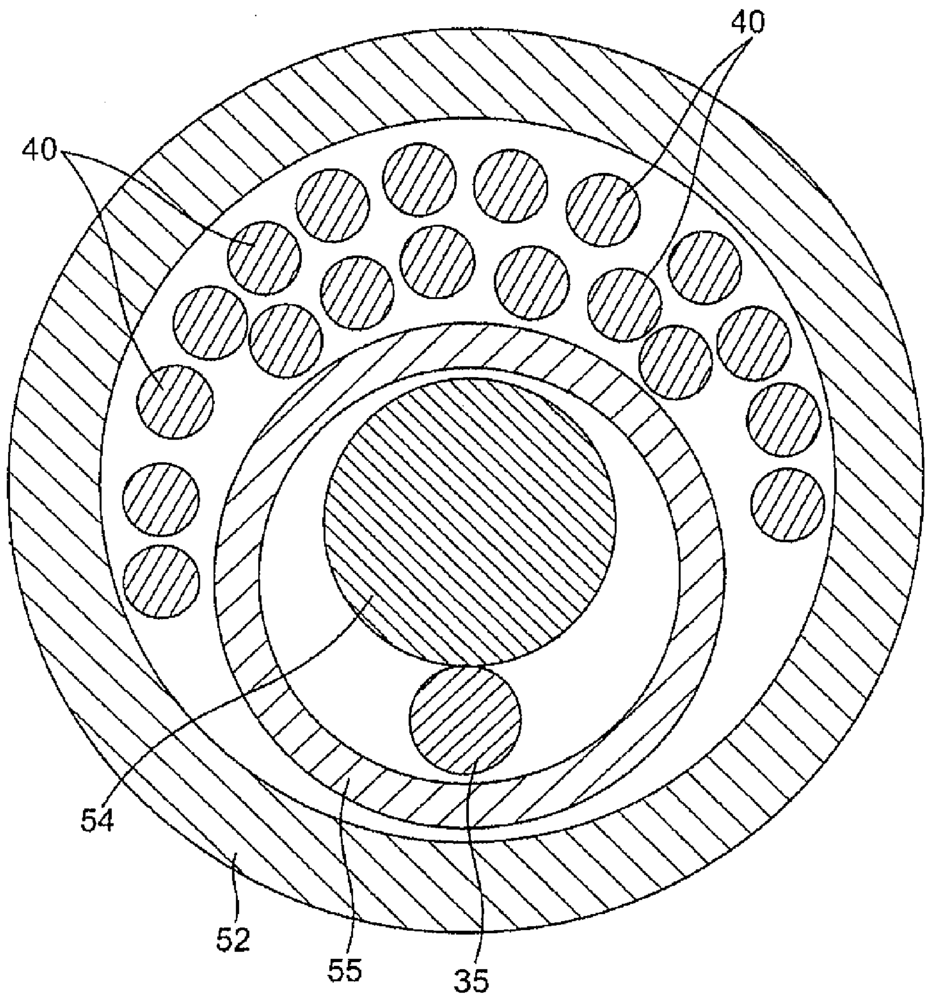

FIG. 6

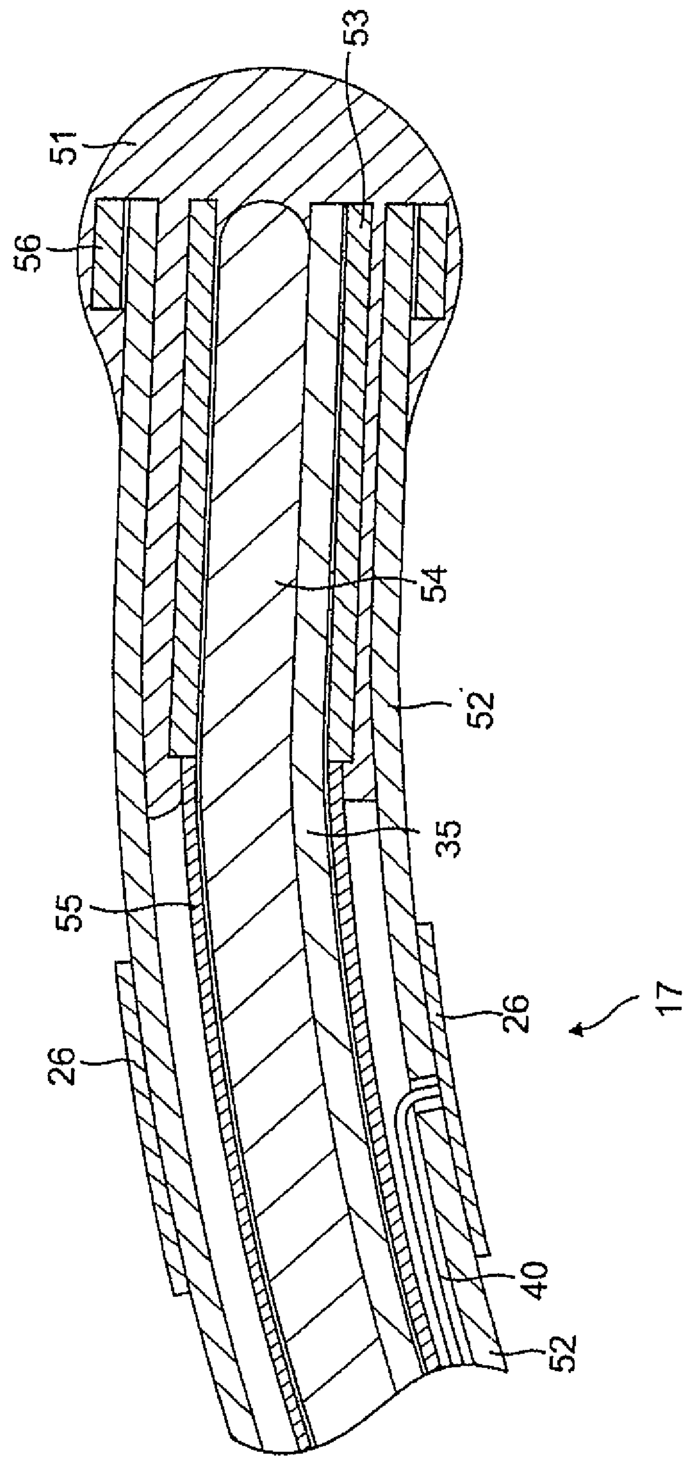

FIG. 7

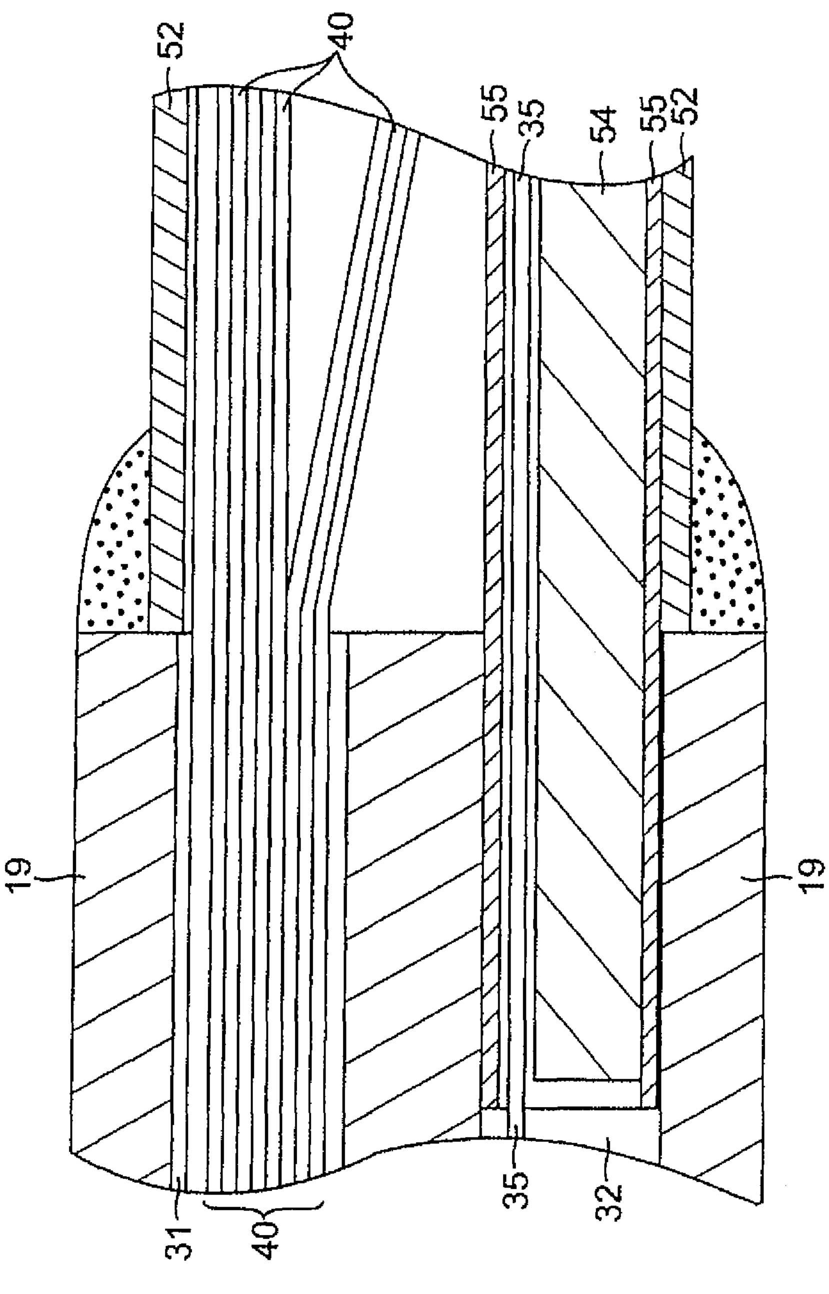

FIG. 8a

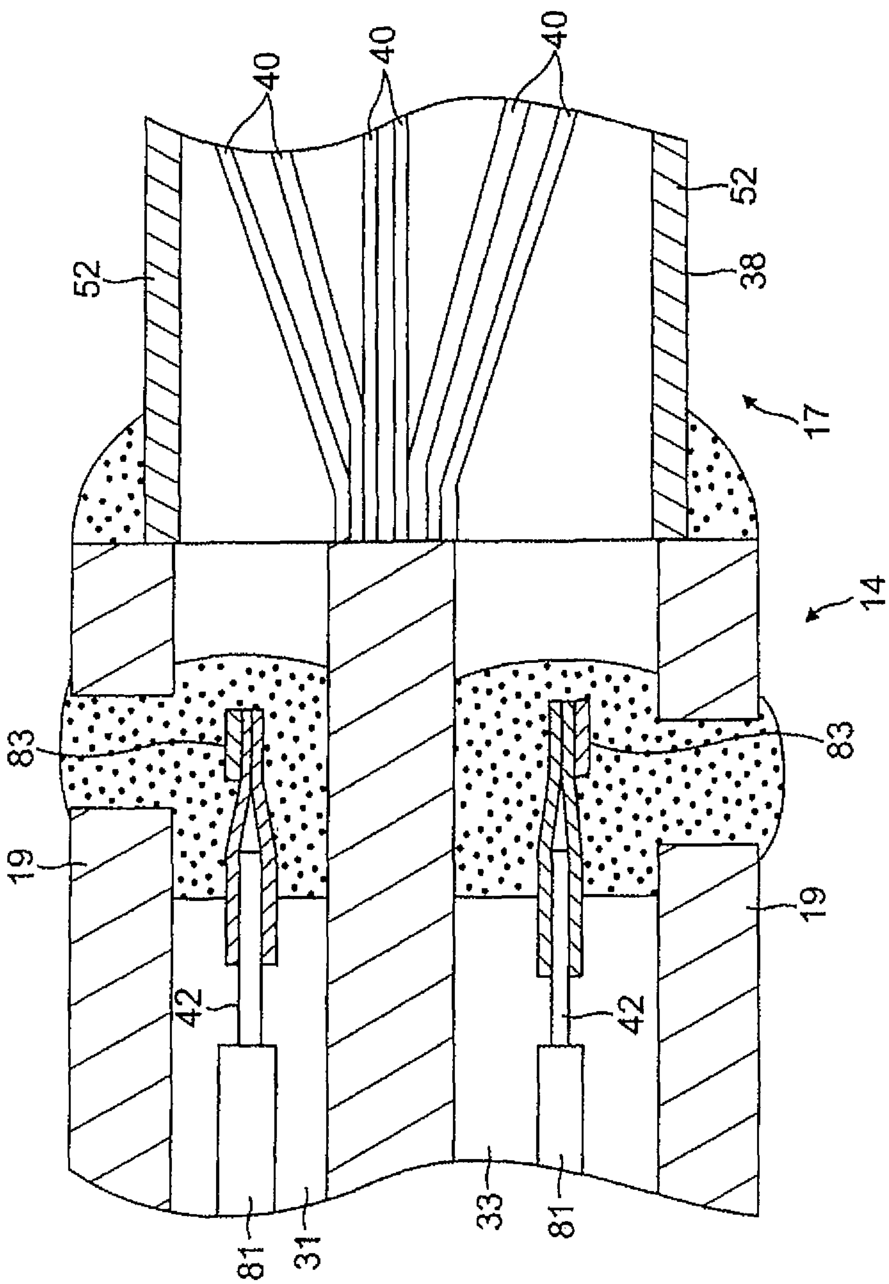

FIG. 8b

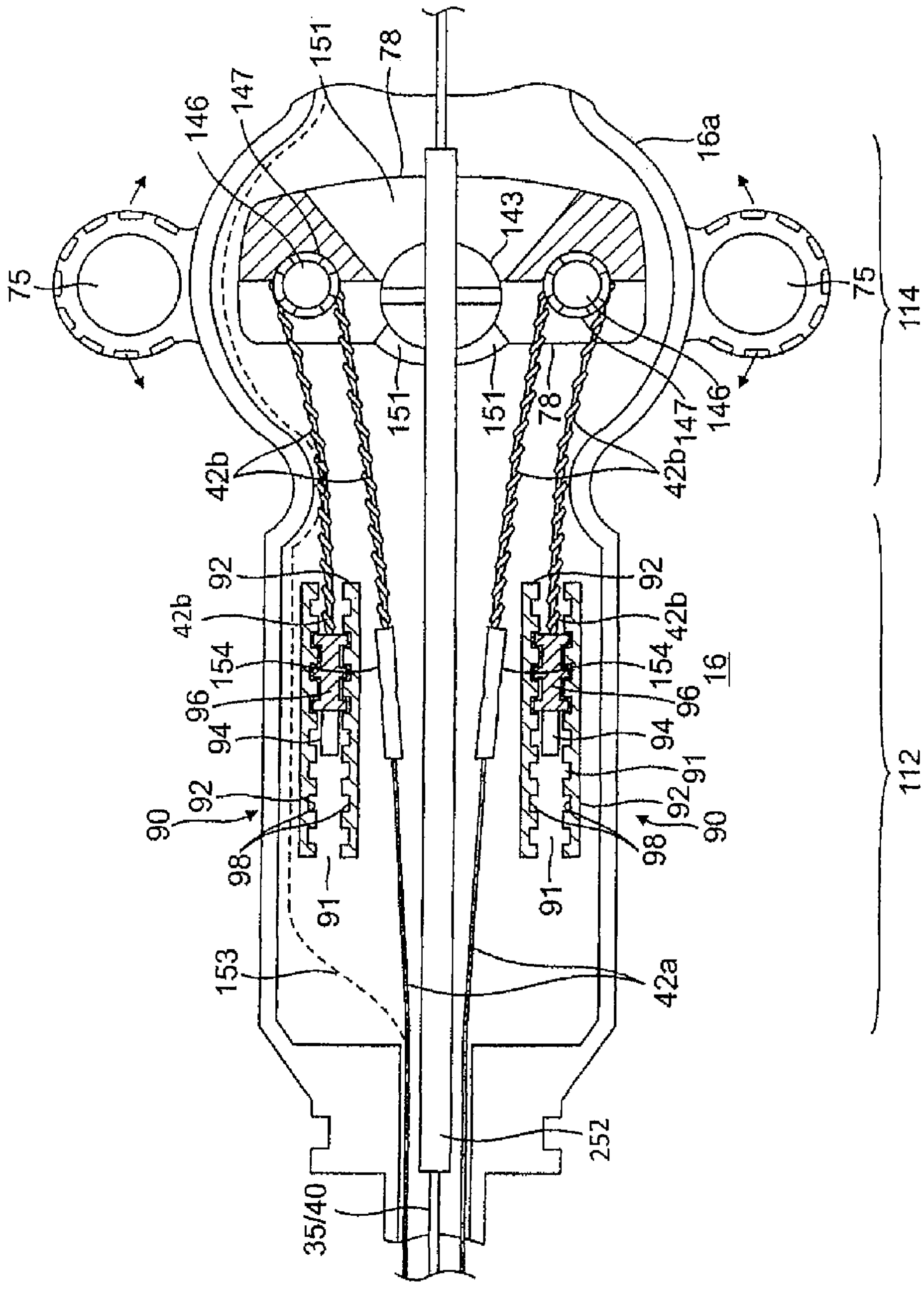
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FIG. 9

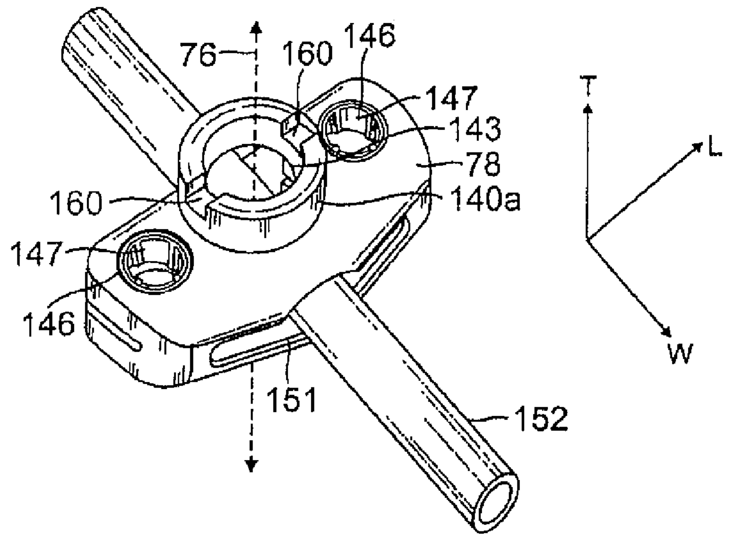
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FIG. 10

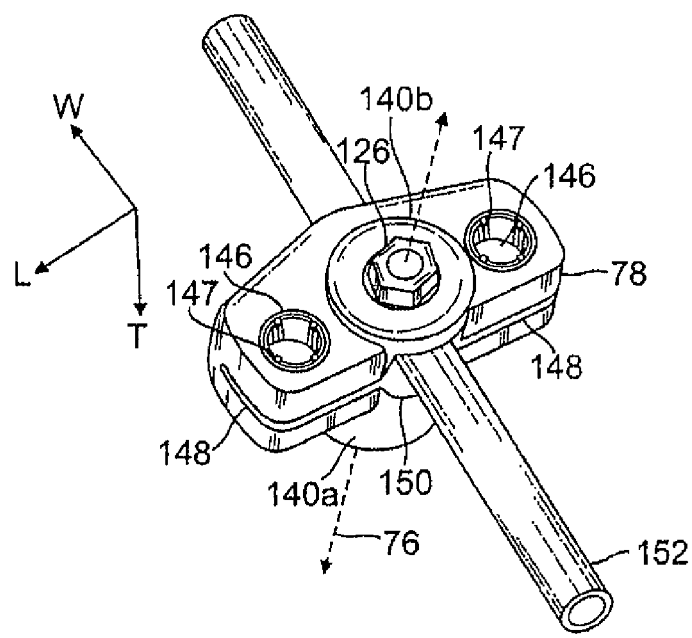
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FIG.11

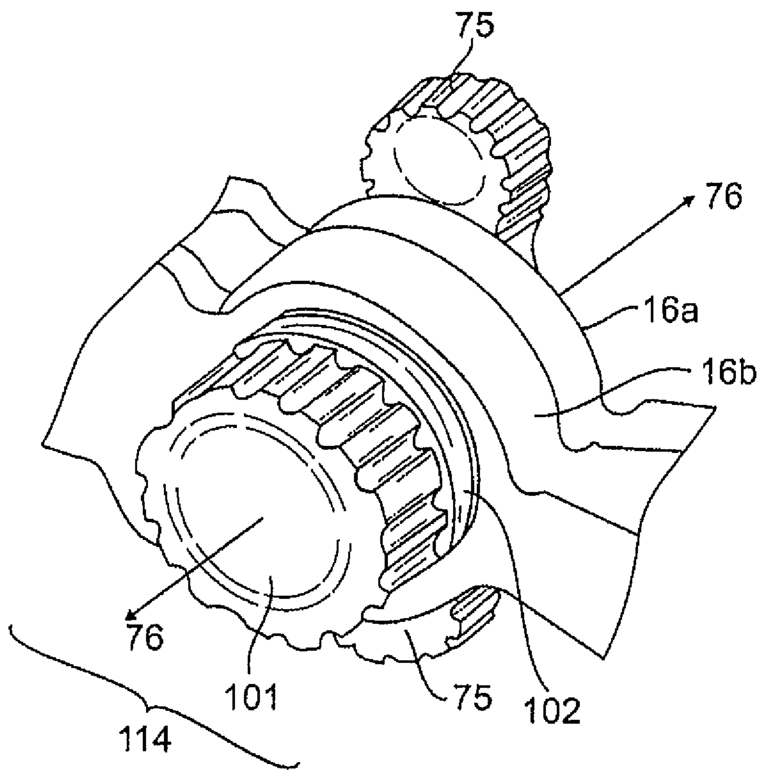

FIG. 20

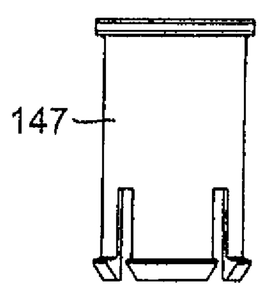

FIG. 12

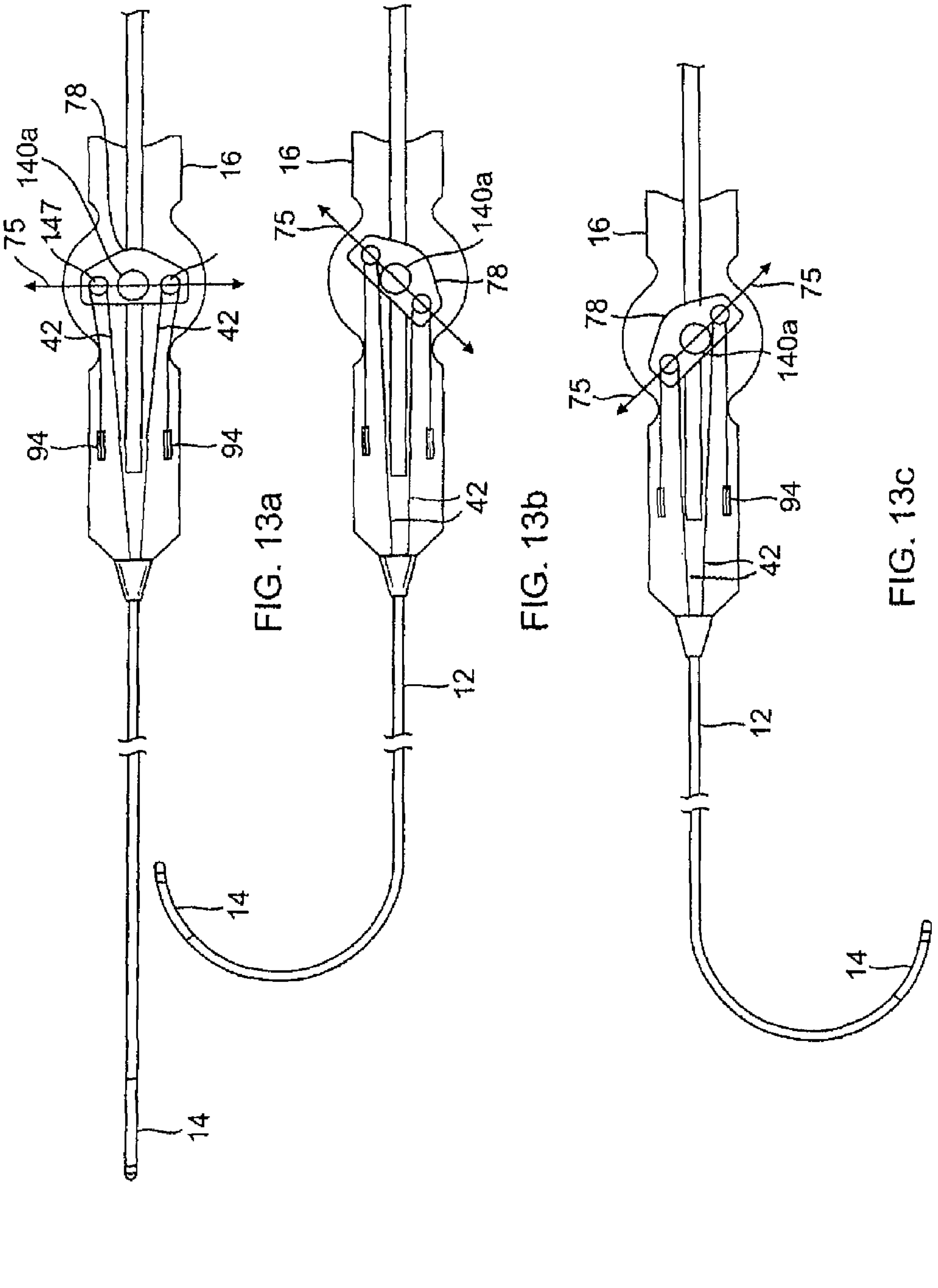

FIG. 13a

FIG. 13b

FIG. 13c

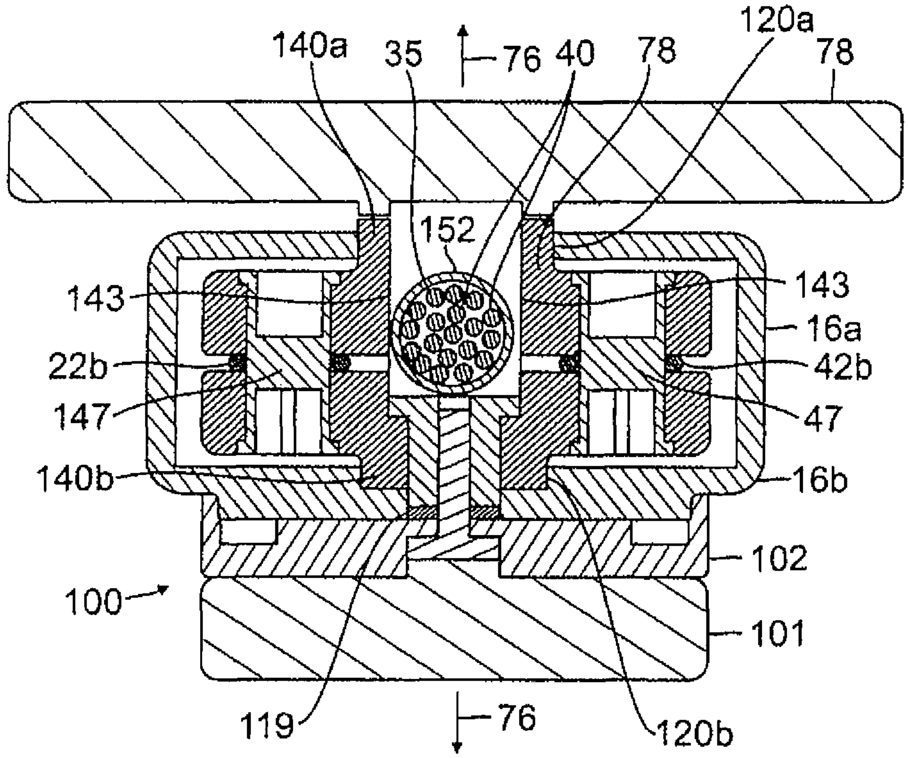

FIG. 14

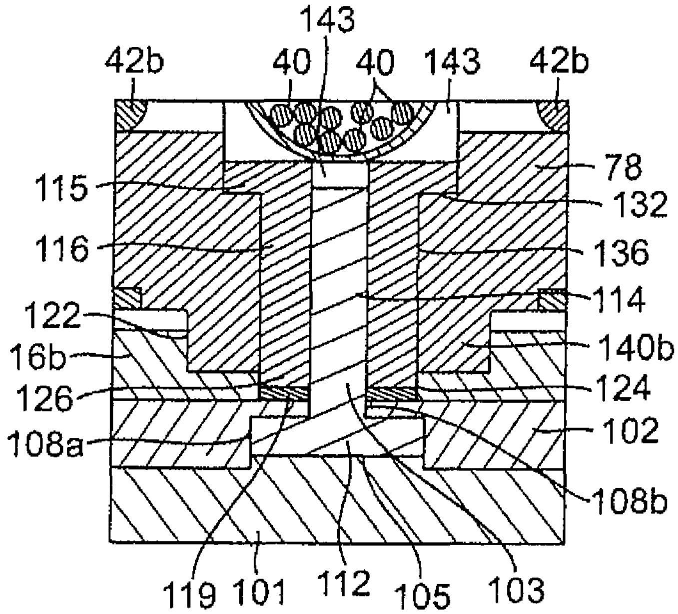

FIG. 14a

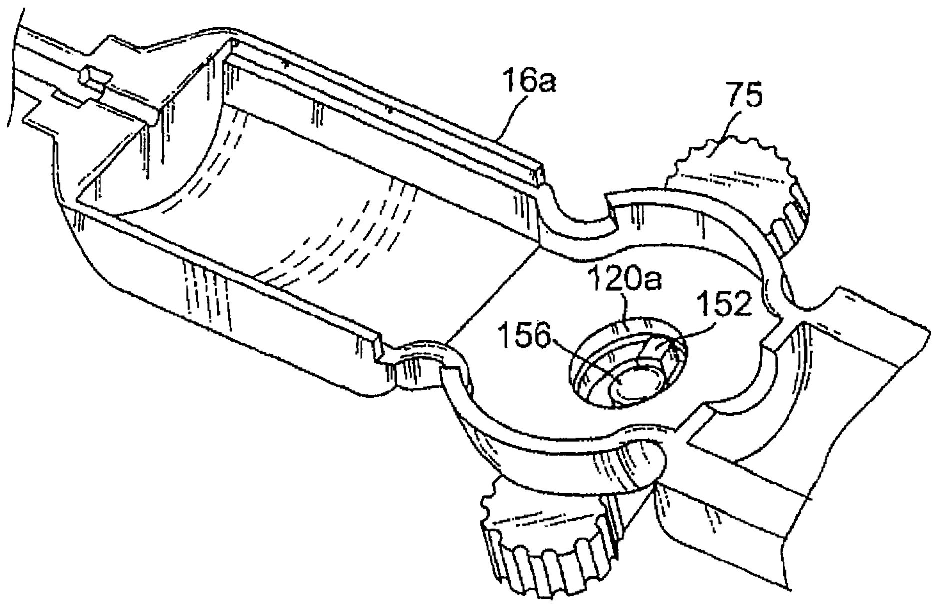

FIG. 15

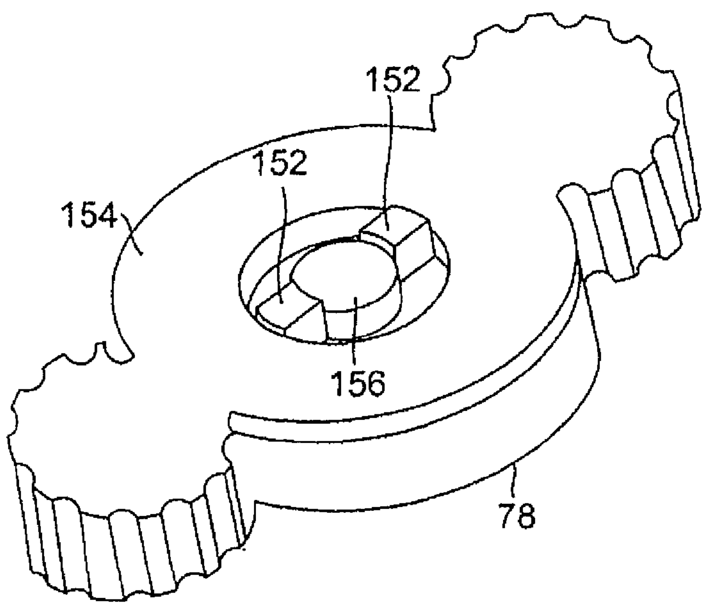

FIG. 16

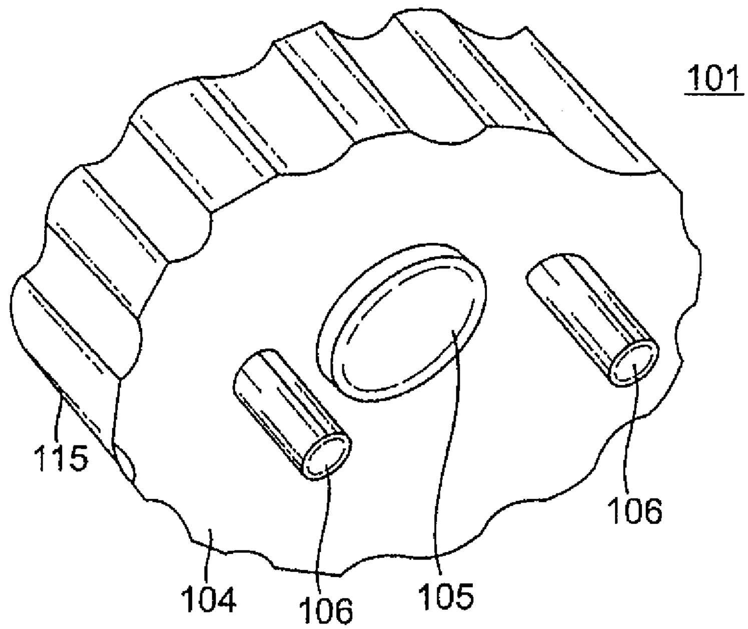

FIG. 17

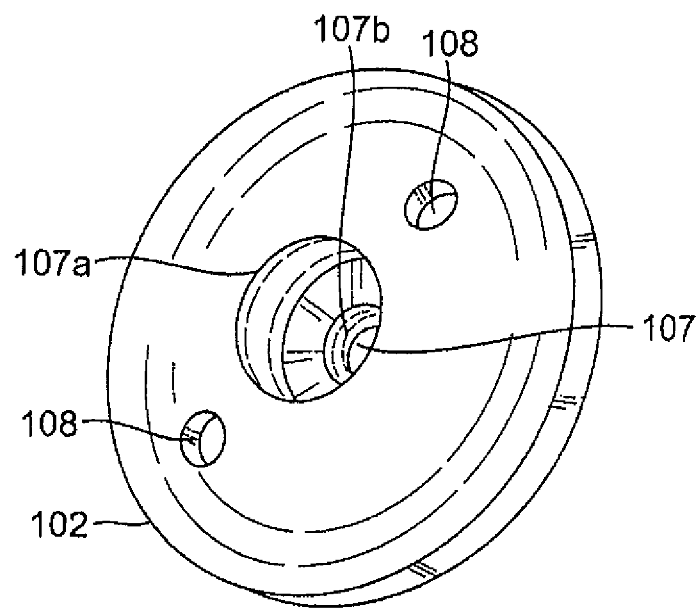

FIG. 18

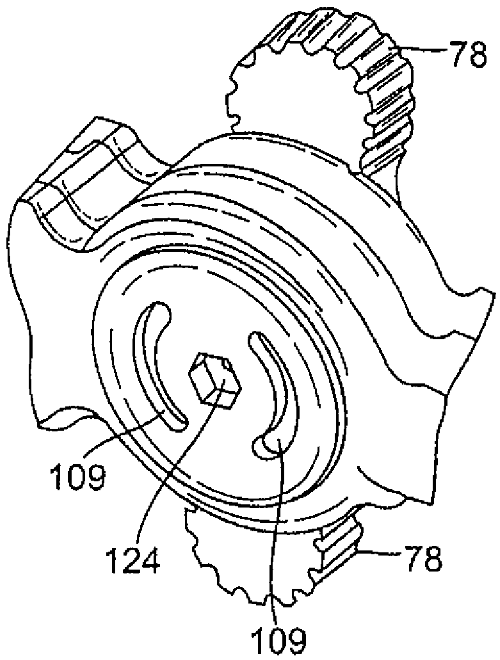

FIG. 19

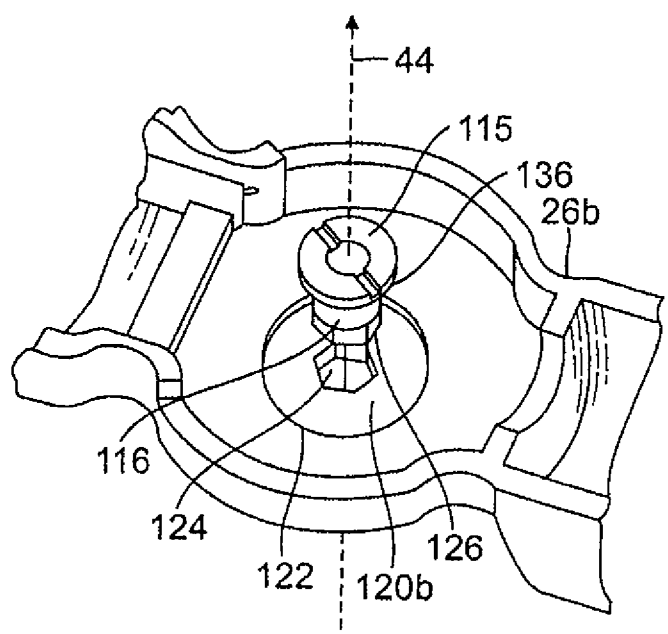

FIG. 21

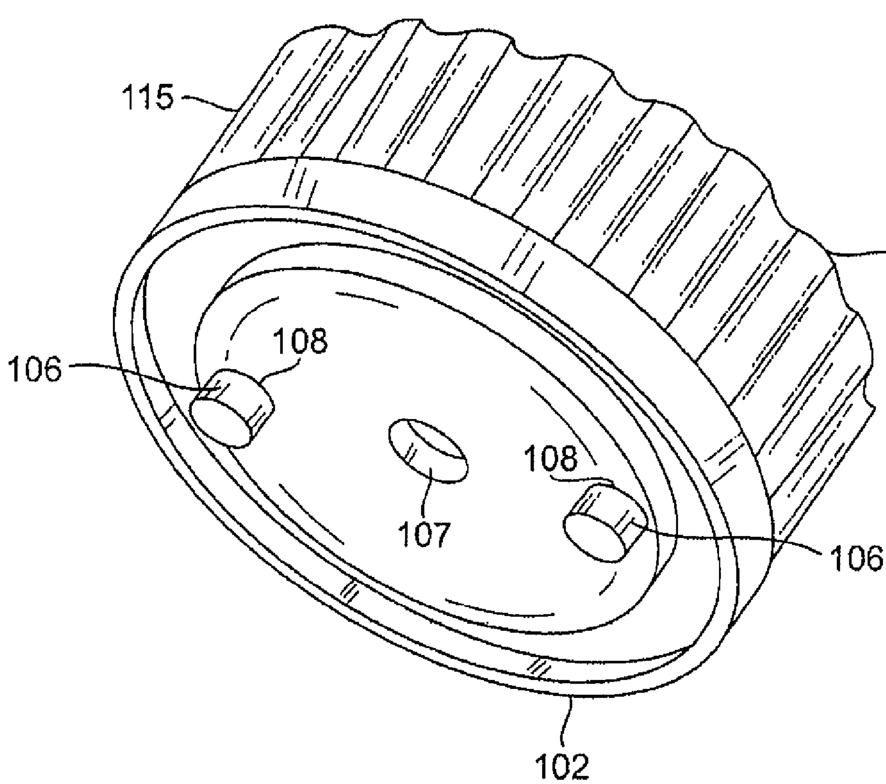

FIG. 22

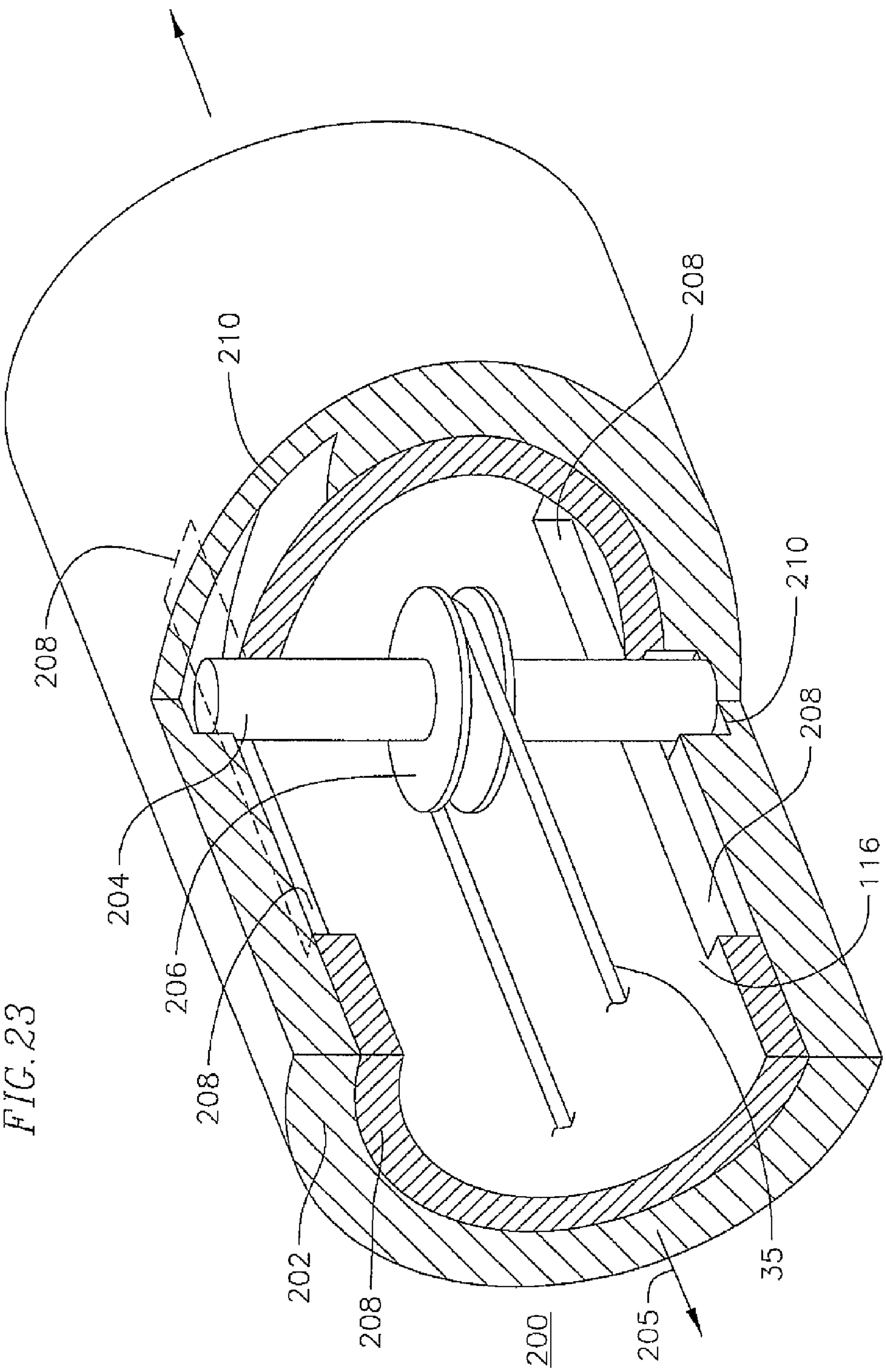

FIG. 23

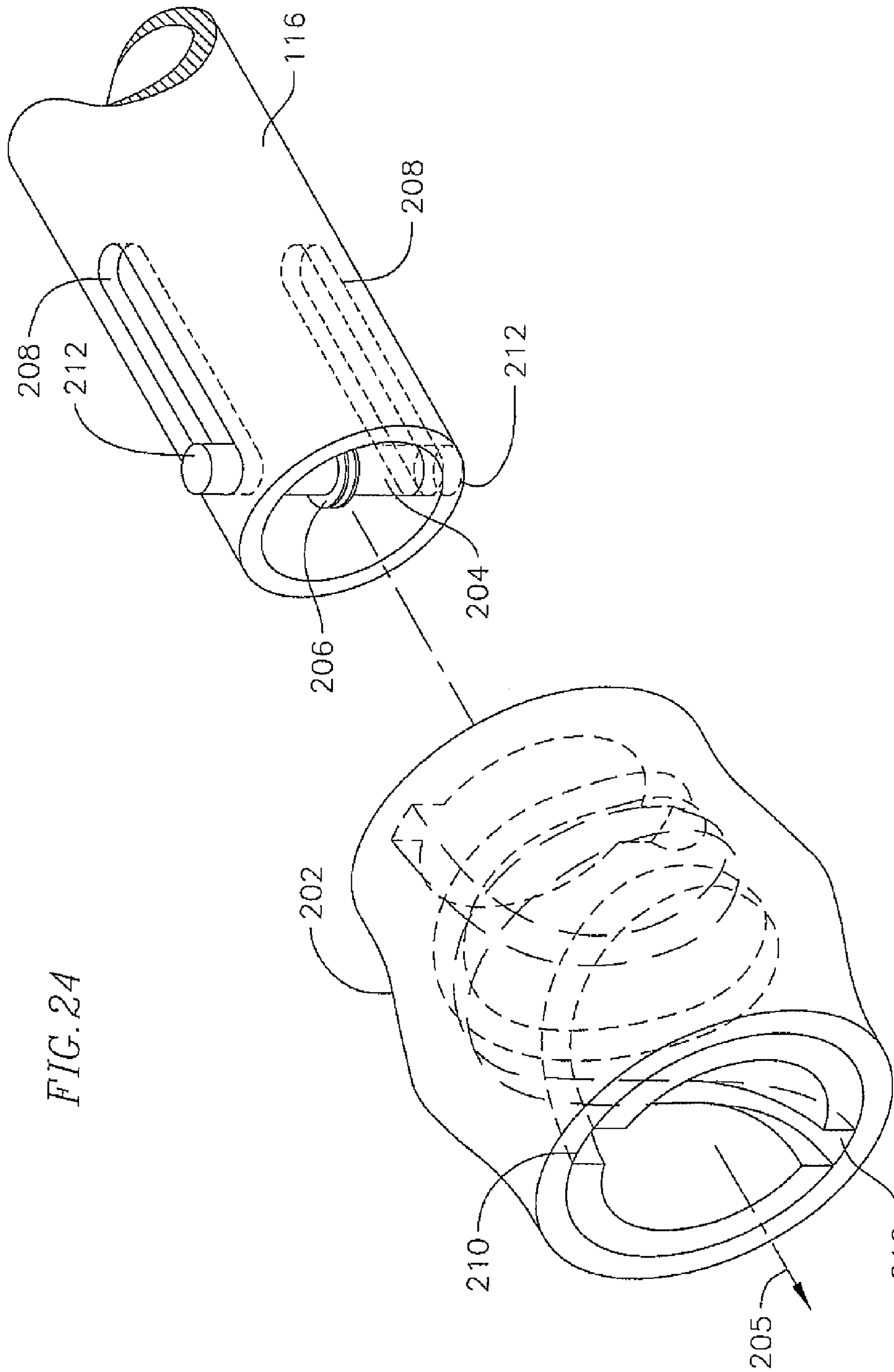

FIG. 24

CONTROL HANDLE WITH ROTATIONAL CAM MECHANISM FOR CONTRACTION/DEFLECTION OF MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATION(S)

This application is a continuation of an claims priority to and the benefit of U.S. patent application Ser. No. 12/960,286 filed Dec. 3, 2010, now U.S. Pat. No. 8,617,087 issued Dec. 31, 2013, the entire contents of which is incorporated herein by reference.

FIELD OF INVENTION

This invention relates to a catheter, in particular, a control handle having multiple control mechanisms for deflecting and contracting portions of a medical device.

BACKGROUND

Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity. Atrial fibrillation is a common sustained cardiac arrhythmia and a major cause of stroke. This condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue substrate. Various approaches have been developed to interrupt wavelets, including surgical or catheter-mediated atriotomy. Prior to treating the condition, one has to first determine the location of the wavelets. Various techniques have been proposed for making such a determination, including the use of catheters with a mapping assembly that is adapted to measure activity within a pulmonary vein, coronary sinus or other tubular structure about the inner circumference of the structure. One such mapping assembly has a tubular structure comprising a generally circular main region generally transverse and distal to the catheter body and having an outer circumference and a generally straight distal region distal to the main region. The tubular structure comprises a non-conductive cover over at least the main region of the mapping assembly. A support member having shape-memory is disposed within at least the main region of the mapping assembly. A plurality of electrode pairs, each comprising two ring electrodes, are carried by the generally circular main region of the mapping assembly.

In use, the electrode catheter is inserted into a guiding sheath which has been positioned a major vein or artery, e.g., femoral artery, and guided into a chamber of the heart. Within the chamber, the catheter is extended past a distal end of the guiding sheath to expose the mapping assembly. The catheter is maneuvered through movements that include deflection of a distal portion of the catheter so that the mapping assembly is positioned at the tubular region in the heart chamber. The ability to control the exact position and orientation of the catheter and also the configuration of the mapping assembly is critical and largely determines how useful the catheter is.

Steerable catheters are generally well-known. For example, U.S. Pat. No. Re 34,502 describes a catheter having a control handle comprising a housing having a piston chamber at its distal end. A piston is mounted in the piston chamber and is afforded lengthwise movement. The proximal end of the elongated catheter body is attached to the piston. A puller wire is attached to the housing and extends through the piston, through the catheter body, and into a tip section at the distal end of the catheter body. The distal end of the puller wire is anchored in the tip section of the catheter. In this arrangement, lengthwise movement of the piston relative to the housing results in deflection of the catheter tip section.

The design described in U.S. Pat. No. RE 34,502 is generally limited to a catheter having a single puller wire. If bi-directional deflection is desired, more than on puller wire becomes necessary. Moreover, if more control is desired, such as a contraction of the mapping assembly, an additional puller wire is needed. Space is limited within a control handle and operation of puller wire control mechanisms must not interfere with components that extend through the control handle, such as lead wires, cables, and irrigation tubing. Moreover, it is desirable that the control mechanisms be arranged such that the catheter can be operated single-handedly by the user. Accordingly, a desire exists for a control handle capable of moving three puller wires for at least two independent movements, such as bi-directional deflection of the catheter shaft and contraction of the mapping assembly, preferably through a single-handed manipulation of the user. A further desire exists for a deflection/contraction mechanism without excessive stress or kinking to the tensile component by which deflection/contraction is accomplished, whether it is a puller wire, a contraction wire, or another component.

SUMMARY OF THE INVENTION

The present invention is directed to a medical device which has a distal member with a configuration that can be changed by means of a control handle with a control assembly employing a rotational cam, a shaft, and a pulley, where the rotational cam is rotationally mounted on a portion of the control handle for rotation by a user. The rotational cam operates on the shaft to move it proximally or distally depending on the direction of rotation which in turn rotates the pulley to draw or release a puller wire to change the configuration of the distal member of the medical device. The shaft is oriented along a diameter of the control handle. The shaft has two ends which extends through two axial guide slots in the portion of the control handle to sit two opposing helical tracks formed on inner surface of the rotational cam. The guide slots are parallel with the longitudinal axis of the control handle and therefore maintain the shaft's diametrical orientation as the rotational cam is rotated to move the shaft proximally or distally. Actuation of the puller wire by means of the control assembly can result in a change of the distal member's configuration, including deflection, contraction and/or expansion.

In one embodiment, a catheter for use in a patient's heart, especially for mapping a tubular region of the heart, includes a catheter body and a deflectable intermediate section distal the catheter body. Distal the intermediate section is a mapping assembly that has a generally circular portion adapted to sit on or in a tubular region of the heart. A control handle of the catheter allows for single-handed manipulation of various control mechanisms that can deflect the intermediate section and contract the mapping assembly by means of a deflection control assembly and a rotational control assembly. The deflection control assembly has a deflection arm and a rocker member. The rotational control assembly has an outer rotational cam, a shaft and a pulley. A pair of puller members are responsive to the deflection control assembly to bi-directionally deflect the intermediate section. A third puller member is responsive to the rotational control assembly to contract the generally circular portion of the mapping assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings. It is understood that selected structures and features have not been shown in certain drawings so as to provide better viewing of the remaining structures and features.

FIG. **1** is a top plan view of one embodiment of the catheter of the present invention.

FIG. **2***a* is a side cross-sectional view of an embodiment of a junction of a catheter body and an intermediate section, taken along a first diameter.

FIG. **2***b* is a side cross-sectional view of the embodiment of the junction of FIG. **2***a*, taken along a second diameter generally perpendicular to the first diameter.

FIG. **3** is a side view of a distal portion of the catheter of FIG. **1**, including an intermediate section and a mapping assembly.

FIG. **4** is a longitudinal cross-sectional view of the intermediate section of FIG. **3**, taken along line **4-4**.

FIG. **5** is a schematic view of the mapping assembly showing one arrangement of the ring electrodes.

FIG. **6** is a longitudinal cross-sectional view of the mapping assembly of FIG. **3** along line **6-6**.

FIG. **7** is a side cross-sectional view of an embodiment of a distal end of the mapping assembly of FIG. **3**.

FIG. **8***a* is a side cross-sectional view of an embodiment of a junction between the intermediate section and the mapping assembly, taken along a first diameter.

FIG. **8***b* is a side cross-sectional view of an embodiment of a junction between the intermediate section and the mapping assembly, taken along a second diameter generally perpendicular to the first diameter.

FIG. **9** is a top plan view of an embodiment of a control handle housing half including an embodiment of a deflection control assembly.

FIG. **10** is a top perspective view of an embodiment of a rocker member of a deflection control assembly.

FIG. **11** is a bottom perspective view of an embodiment of a rocker member.

FIG. **12** is a side view of an embodiment of a pulley of a deflection control assembly.

FIG. **13***a*-**13***c* are schematics of an embodiment of the deflection control assembly in neutral and rotated configurations.

FIG. **14** is a longitudinal cross section of an embodiment of the deflection control assembly and tension control assembly mounted on a control handle.

FIG. **14***a* is a detailed view of a portion of FIG. **14**, including an embodiment of a retaining nut and a tension screw.

FIG. **15** is a partial perspective view of an embodiment of a first control handle housing half.

FIG. **16** is a perspective view of an embodiment of a deflection arm.

FIG. **17** is a perspective view of an embodiment of a tension control dial.

FIG. **18** is a perspective view of an embodiment of a locking plate.

FIG. **19** is a partial perspective view of a portion of an embodiment of a control handle.

FIG. **20** is a partial perspective view of a portion of an embodiment of a deflection arm and a tension control member mounted on a control handle.

FIG. **21** is a partial perspective view of a portion of an embodiment of a second control handle housing half and a retaining nut, the second control housing half adapted to oppose the first control handle housing half.

FIG. **22** is a perspective view of the tension control dial of FIG. **17** and locking plate of FIG. **18** as assembled.

FIG. **23** is a perspective view of an embodiment of a rotational control assembly.

FIG. **24** is an exploded perspective view of the rotational control assembly of FIG. **23**.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. **1**, the present invention is directed to a catheter **10** with multiple control capabilities for mapping and/or ablation of the heart. In the illustrated embodiment of FIG. **1**, a catheter **10** comprises an elongated catheter body **12**, a deflectable intermediate section **14** at a distal end of the catheter body **12**, a tip section **15** including a mapping assembly **17** at a distal end of the intermediate section **14**, and a multi-functional control handle **16** at a proximal end of the catheter body **12** for controlling portions of the catheter, for example, deflecting the intermediate section **14** and contracting the mapping assembly **17**.

With reference to FIGS. **2**A and **2**B, the catheter body **12** comprises a single, central or axial lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** may be of any suitable construction and made of any suitable material. A suitable construction comprises an outer wall **22** made of a polyurethane or nylon. The outer wall **22** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the tip section of the catheter **10** will rotate in a corresponding manner.

The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 French. Likewise the thickness of the outer wall **22** is not critical. The inner surface of the outer wall **22** is lined with a stiffening tube **20**, which can be made of any suitable material, e.g., polyimide. The stiffening tube **20** is held in place relative to the outer wall **22** at the proximal end of the catheter body **12**. A first glue joint **23** is made between the distal ends of the stiffening tube **20** and the outer wall **22** by a fast drying glue, e.g. Super Glue® Thereafter a second glue joint **25** is formed between the proximal ends of the stiffening tube **20** and outer wall **22** using a slower drying but stronger glue, e.g., polyurethane.

The stiffening tube, along with the braided outer wall **22**, provides improved torsional stability while at the same time minimizing the wall thickness of the catheter, thus maximizing the diameter of the single lumen. The outer diameter of the stiffening tube **20** is about the same as or slightly smaller than the inner diameter of the outer wall **22**. Polyimide tubing is suitable because it may be very thin walled while still providing very good stiffness. This maximizes the diameter of the central lumen **18** without sacrificing strength and stiffness. Polyimide material is typically not used for stiffening tubes because of its tendency to kink when bent. However, it has been found that, in combination with an outer wall **22** of polyurethane, nylon or other similar material, particularly having a stainless steel braided mesh, the tendency for the polyimide stiffening tube **20** to kink when bent is essentially eliminated with respect to the applications for which the catheter is used.

In one embodiment, the outer wall **22** has an outer diameter of about 0.092 inch and an inner diameter of about 0.063 inch and the polyimide stiffening tube **20** has an outer diameter of about 0.0615 inch and an inner diameter of about 0.052 inch.

As shown in FIGS. **2**A, **2**B and **4**, the intermediate section **14** comprises a shorter section of tubing **19** with multiple off-axis lumens, for example, first, second, third and fourth lumens **30**, **31**, **32** and **33**. The tubing **19** is made of a suitable non-toxic material which is preferably more flexible than the catheter body **12**. A suitable material for the tubing **19** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The outer diameter of the intermediate section **14**, like that of the catheter body **12**, is preferably no greater than about 8 French. The size of the lumens is not critical. In one embodiment, the intermediate section has an outer diameter of about 7 French (0.092 inch) and the lumens are generally about the same size, having a diameter of about 0.022 inch, or selected lumens can have a slightly larger diameter of about 0.036 inch.

A means for attaching the catheter body **12** to the intermediate section **14** is illustrated in FIGS. **2**A and **2**B. The proximal end of the intermediate section **14** comprises an inner counter bore **24** that receives the outer surface of the polyimide stiffener **20**. The intermediate section **14** and catheter body **12** are attached by glue **29** or the like.

As shown in FIGS. **2**A and **2**B, extending through the single lumen **18** of the catheter body **12** are various components, for example, lead wires and multiple puller members, and any other wires or cables. Longitudinal movement of the puller members relative to the catheter body **12** enable user control of various parts of the catheter via the control handle. In one embodiment, the puller members include a pair of deflection puller members **42** for deflecting the intermediate section **14** and a contraction puller member **35** for adjusting the mapping assembly **17** of the tip section **15**.

A single lumen catheter body **12** can be preferred over a multi-lumen body because the single lumen **18** body can permit better tip control when rotating the catheter **10**. The single lumen **18** permits the components passing therethrough to float freely within the catheter body. If such components were restricted within multiple lumens, they can build up energy when the handle **16** is rotated, resulting in the catheter body **12** having a tendency to rotate back if, for example, the handle is released, or if bent around a curve, to flip over, either for which are undesirable performance characteristics.

A deflection puller member **42** extends through the central lumen **18** of the catheter body **12** and into the second lumen **31** of the intermediate section **14**. Another deflection puller member **42** extends through the central lumen **18** and into the fourth lumen **33** of the intermediate section **14**. The distal ends of the deflection puller members **42** are anchored to the wall of the tubing **19** near the distal end of the intermediate section **14** by means of T-anchors **83** (FIG. **8**B). In the intermediate section **14**, each deflection puller members **42** extends through a plastic, e.g., Teflon®, sheath **81**, which prevents the deflection puller members **42** from cutting into the wall of the tubing **19** of the intermediate section **14** when the intermediate section **14** is deflected.

As shown in FIG. **2**B, compression coils **44** in surrounding relation to the deflection puller members **42** extend from the proximal end of the catheter body **12** to the proximal end of the intermediate section **14**. The compression coils **44** are made of any suitable metal, e.g., stainless steel. The compression coils **44** are tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coils **44** is preferably slightly larger than the diameter of the puller wires **42**. For example, when a puller member **42** has a diameter of about 0.007 inches, the compression coil **44** preferably has an inner diameter of about 0.008 inches. The Teflon® coating on the puller member **42** allows them to slide freely within the compression coils **44**. The outer surface of the compression coils **44** is covered by a flexible, non-conductive sheath **27** to prevent contact between the compression coils **44** and other components, such as lead wires and cables, etc. A non-conductive sheath can be made of polyimide tubing.

The compression coils **44** are anchored at their proximal ends to the proximal end of the stiffening tube **20** in the catheter body **12** by glue joint **50** (FIG. **2**B) and at its distal end near the proximal end of the intermediate section **14** in the second lumen **31** and fourth lumen **33** by glue joints **49** (FIG. **2**B).

With reference to FIG. **3**, at the distal end of the intermediate shaft **14** is the mapping assembly **17**. The mapping assembly **17** comprises a generally straight proximal region **38** and a generally circular main region **39**. The proximal region **38** is mounted on the intermediate section **14**, as described in more detail below, so that it is generally a linear extension of the intermediate section **14**. In one embodiment, the proximal region **38** has an exposed length, e.g., not contained within the intermediate section **14**, ranging from about 3 mm to about 12 mm, more preferably about 3 mm to about 8 mm, still more preferably about 5 mm, but can vary as desired.

The generally circular main region **39** is generally traverse, if not also perpendicular, to the catheter body **12**. The generally circular main region **39** can form a flat circle or can be very slightly helical. In one embodiment, the main region **39** has an outer diameter ranging from about 10 mm to about 25 mm, more preferably about 12 mm to about 20 mm. The generally circular main region **39** can curve in a clockwise direction or a counterclockwise direction. As shown in FIGS. **5**, **6** and **7**, the mapping assembly **17** is formed of a non-conductive cover or tubing **52** which can have any cross-sectional shape as desired. The non-conductive cover **52** can be made of any suitable material, and is preferably made of a biocompatible plastic such as polyurethane or PEBAX. The non-conductive cover **52** can be pre-formed into the desired generally circular shape of the generally circular main region **39**. Alternatively, the shape of the generally circular main region **39** can be defined by a wire or other component extending through the non-conductive cover **52**.

In the depicted embodiment, a pre-formed support member **54** extends through the non-conductive cover **52** to define the shape of the generally circular main region **39**. The support member **54** is made of a material having shape-memory, i.e., that can be straightened or bent out of its original shape upon exertion of a force and is capable of substantially returning to its original shape upon removal of the force. On suitable material for the support member **54** is a nickel/titanium alloy. Such alloys typically comprise about 55% nickel and 45% titanium, but may comprise from about 54% to about 57% nickel with the balance being titanium. A suitable nickel/titanium alloy is Nitinol, which has excellent shape memory, together with ductility, strength, corrosion resistance, electrical resistivity and temperature stability.

A series of ring electrodes **26** are mounted on the non-conductive cover **52** of the generally circular main region **39** of the mapping assembly **17**, as shown in FIG. **5**. The ring electrodes **26** can be made of any suitable solid conductive material, such as platinum or gold, or a combination of platinum and iridium, and mounted onto the non-conductive cover **52** with glue or the like. Alternatively, the ring electrodes **26** can be formed by coating the non-conductive cover **52** with an electrically conducting material, like platinum, gold and/or iridium. The coating can be applied using sputtering, ion beam deposition or an equivalent technique. A suitable mapping assembly is described in U.S. Pat. No. 7,274,957, the entire disclosure of which is hereby incorporated by reference. If desired, additional electrodes (not shown) could be mounted along the intermediate section **14** and/or the generally straight proximal section **38**.

The contraction puller member **35**, for example, a contraction puller wire, is provided to contract the generally circular main region **39** to thereby change or reduce its diameter, for example, when mapping or ablating circular or tubular regions of the heart. The contraction wire **35** has a proximal end anchored in the control handle **16**, which is used to manipulate the contraction wire as described further below. The contraction wire **35** extends through the central lumen **18** of the catheter body **12**, through the third lumen **32** of the intermediate section **14** and into the non-conductive cover **52** of the mapping assembly **17**. The portion of the contraction wire **35** extending through the non-conductive cover **52** is positioned on the side of the generally circular main region **39** closer to the center of the generally circular main region, as best shown in FIG. **6**. The center of the generally circular main region refers to the center of the circle formed by the generally circular main region. With this arrangement, contraction of the generally circular main region **39** is dramatically improved over arrangements where the position of the contraction wire **35** is not so controlled.

As shown in FIGS. **5** and **6**, within the mapping assembly **17**, the contraction wire **35** extends through a plastic tube **55**. In one embodiment, the plastic tube **55** comprise three layers, including an inner layer of polyimide over which a braided layer is formed, the braided layer comprising a braided stainless steel mesh or the like, as is generally known in the art. The braided layer enhances the strength of the plastic tube **55**, reducing the tendency for contraction wire **35** to straighten the preformed curve of the mapping assembly **17**. A thin plastic layer of polytetrafluoroethylene is provided over the braided layer to protect the braided layer from getting tangled with the lead wires **40** within the non-conductive cover **52**. The plastic tube **55** has a proximal end anchored to the distal end of the intermediate section **14** in the third lumen **32** by glue or the like (FIG. **8***a*). The support member **54** extends through the plastic tube **55** with the contraction wire **35** (FIG. **8***a*). The distal ends of the support member **54** and the contraction wire **35** are soldered or otherwise attached to a small stainless steel tube **53** (FIG. **7**). With this arrangement, the relative positions of the contraction wire **35** and the support member **54** can be controlled so that the contraction wire can be positioned on the side of the generally circular region **39** closer to the center of the generally circular region **39**, as described above. The contraction wire **35** on the inside of the curve pulls the support member **54** to the inside of the curve, enhancing contraction of the generally circular region **39**. Further, when the plastic tube **55** includes a braided layer, it keeps the contraction wire **35** from tearing through the non-conductive cover **52**.

A third compression coil **46** is situated within the catheter body **12** and intermediate section shaft **14** in surrounding relation to the contraction wire **35** (FIG. 2A). The third compression coil **46** extends from the proximal end of the catheter body **12** to near the distal end of the third lumen **32** of the intermediate section **14**. The third compression coil **46** is made of any suitable metal, e.g., stainless steel, and is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the third compression coil **46** is preferably slightly larger than the diameter of the contraction wire **35**. The outer surface of the compression coil **46** is covered by a flexible, non-conductive sheath **68**, e.g., made of polyimide tubing. The third compression coil **46** can be formed of a wire having a square or rectangular cross-sectional area, which makes it less compressible than a compression coil formed from a wire having a circular cross-sectional area. As a result, the third compression coil **46** keeps the catheter body **12**, and particularly the intermediate section **14**, from deflecting when the contraction wire **35** is manipulated to contract the mapping assembly **17** as it absorbs more of the compression.

The third compression coil **46** is anchored at its proximal end to the outer wall **20** of the catheter body **12** by the proximal glue joint **50** and to the intermediate section **14** by distal glue joint **72**.

It is understood that glue joints throughout the catheter **10** may comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made in the tubing walls. Such a hole may be formed, for example, by a needle or the like that punctures the tubing walls where the needle is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to wick around the component(s) within the tubing to form a glue joint about the entire circumference of the component(s).

In the depicted embodiment of FIG. **7**, the distal end of the mapping assembly **17** is sealed closed with a dome **51** of polyurethane glue or the like. A short ring **56**, made of metal or plastic, and e.g., polyamide, is mounted within the distal end of the non-conductive cover **52**. The short ring **56** prevents the distal end of the non-conductive cover **52** from collapsing, there by maintaining the diameter of the non-conductive cover at its distal end.

At the junction of the intermediate section **14** and the mapping assembly **17** as shown in FIGS. **8***a* and **8***b*, the non-conductive cover **52** is attached to the intermediate section **14** by glue or the like. The plastic tube **55** has its proximal end inserted and glued in the distal end of the intermediate section **14**. The glue (not shown) from the plastic tube **55** can further serve to anchor the distal end of the third compression coil **46** in place within the third lumen **32**. The support member **54** extends from the third lumen **32** into the plastic tube **55** within the non-conductive cover **52**. The proximal end of the support member **54** terminates a short distance proximally from the distal end of the third lumen **32**, approximately about 5 mm, so as not to adversely affect the ability of the intermediate section **14** to deflect. However, if desired, the proximal end of the support member **54** can extend proximally further into the intermediate section **14** and/or the catheter body **12**.

The lead wires **40** attached to the ring electrodes **26** extend through the first lumen **30** of the intermediate section **14** (FIG. 2A), through the central lumen **18** of the catheter body **12**, through the control handle **16**, and terminate at their proximal end in a connector (not shown) which is connected to an appropriate monitor or other device for receiving and displaying the information received from the ring electrodes **26**. The portion of the lead wires **40** extending through the central lumen **18** of the catheter body **12**, control handle **16** and proximal end of the intermediate section **14** is enclosed within a protective sheath **62**, which can be made of any suitable material, such as polyimide. The protective sheath **62** is anchored at its distal end to the proximal end of the intermediate section **14** by gluing it in the lead wire lumen **30** with polyurethane glue or the like to form glue joint **73**.

The lead wires **40** are attached to the ring electrode **26** by any conventional technique. In one embodiment, each ring electrode **26** is mounted by first forming a hole in the non-conductive cover **52**. An electrode lead wire **40** is fed through the hole, and the ring electrode **26** is welded in place over the lead wire and non-conductive cover **52**.

With reference to FIG. **1**, the control handle **16** comprises a generally elongated handle housing, which can be made of any suitable rigid material, such as plastic configured through a suitable molding process. In the illustrated embodiment, the housing includes two opposing halves **16***a* and **16***b* that generally mirror each other and are joined by glue, sonic welding or other suitable means along a longitudinal peripheral seam **28** around the housing. In the illustrated embodiment, the cross section of the handle **16** formed by the opposing halves changes along the length of the handle. A more distal portion **112** has a smaller, generally rectangular cross section. A mid-portion **114** has a larger, generally rectangular cross section. A more proximal portion **116** has a generally circular cross section.

In the illustrated embodiment of FIGS. **1** and **9**, the control handle **16** houses components of a deflection control assembly **74** in the mid-portion **114**. The deflection control assembly includes a deflection member or arm **75** that can be directly manipulated by an operator to control deflection of the intermediate section **14**. The deflection arm **75** is rotatable about an axis **76** that is generally transverse or perpendicular to the longitudinal axis of the control handle. The deflection control assembly **74** has a rotatable rocker member **78** that acts on the deflection puller members **42** to deflect the intermediate section **14**.

The rocker member **78** has a length L dimension, a width W dimension and a thickness T dimension (FIGS. **10** and **11**). Along its thickness dimension T, the rocker member. **78** is configured with two opposing annular formations **140***a* and **140***b* that define a central hole or passage **143** that extends through its entire thickness. The central hole **143** is aligned with the rotational axis **76** of the deflection arm **75**. Along its length dimension L, the rocker member **78** also has two smaller holes **146** that oppose each other across the central hole **143**. In each hole sits a pulley **147**, for example, a snap bearing (FIG. **12**), that has a rotational axis parallel to the axis **76**. Each deflection puller member **42** enters the rocker member through slots **148** and a portion is wound around a respective pulley **147**.

As understood by one of ordinary skill in the art, the rocker member **78** and the pulleys **147** are arranged such that rotation of the rocker member in one direction about the axis **76** draws back one puller member **42** to deflect the intermediate section **14** in that direction. With reference to FIGS. **13***a*-**13***c*, as the rocker member **78** is rotated by means of the deflection arm (as represented by line **75**), the pulleys **147** are displaced from a neutral position (FIG. **13***a*) with one pulley **147** drawing a puller member **42** on one side of the catheter body **12** against its anchored proximal end for deflecting the intermediate section **14** toward that side (FIGS. **13***b* and **13***c*).

Each deflection puller member **42** may comprise multiple segments. As illustrated in FIG. **9**, each deflection puller member has a distal puller wire **42***a* and a proximal fiber **42***b* that are joined or connected at a location within the control handle **16** distal the rocker member **78**. The puller wire **42***a* and the tensile fiber **42***b* of each deflection puller member are connected or secured to each other by a connector **154**, e.g., a crimped brass ferrule covered by shrink tubing. Each puller wire **42***a* extends through the catheter body **12** and the intermediate section **14**. Each tensile fiber **42***b* extends inside the control handle **16**. In this manner, it is the more flexible tensile fibers **42***b* that interact with the pulleys **147** and undergo repeated bending and straightening during deflection operations, as they are less prone to bending stress and fatigue failure.

Each puller wire **42***a* is made of any suitable metal, such as stainless steel or Nitinol. Preferably each puller wire has a low friction coating, such as a coating of Teflon® or the like. Each puller wire has a diameter preferably ranging from about 0.006 inch to about 0.012 inch. Preferably both of the puller wires have the same diameter. Flat puller wires may be used in place of round puller wires. Their cross sectional dimensions should be such that they provide comparable tensile strengths as round puller wires.

Each tensile fiber **42***b* may be of a high modulus fiber material, preferably having an ultimate tensile strength substantially in the range of 412-463 ksi (2480-3200 Mpa) such as High Molecular Density Polyethylene (e.g., Spectra™ or Dyneema™), a spun para-aramid fiber polymer (e.g., Kevlar™) or a melt spun liquid crystal polymer fiber rope (e.g., Vectran™), or a high strength ceramic fiber (e.g., Nextel™). The term fiber is used herein interchangeably with the term fibers in that the tensile fiber may be of a woven or braided construction. In any case, these materials tend to be flexible, providing suitable durability when used in wrapped engagement with the pulleys and the like for greater throw in deflecting the catheter tip. Further, they are substantially nonstretching, which increases the responsiveness to the manipulation of the control handle, and nonmagnetic so that they generally appear transparent to an MRI. The low density of the material causes it to be generally transparent to an x-ray machine. The materials can also be nonconductive to avoid shorting. Vectran™, for example, has high strength, high abrasion resistance, is an electrical insulator, nonmagnetic, is polymeric, and has low elongation under sustained loading conditions.

In the illustrated embodiment of FIG. **9**, each tensile fiber **42***b* extends proximally from the connector **154** toward the rocker member **78** where each is wound around a respective pulley **147** and turns about 180 degrees to double back toward the distal end of the control handle. Each proximal end of the tensile fiber **42***b* is anchored by an anchor assembly **90** that includes a pair of racks **92**, a slug **94** and a stop **96**. The proximal end of each tensile fiber **42***b* extends between a channel **91** defined by the pair of racks **92**, and the proximal end of each tensile fiber is encased within a molded member or slug **94** sized to fit in and translate in the channel **91**. Proximal the slug are the stops **96** that are adjustably positioned in a selected location along the racks **92**, for example, by means of interlocking teeth **98** formed in the racks and the stops to releasably lock in the selected position against movement. The stops **96** are formed so that each respective tensile fiber **42***b* can slide through or below them while blocking the slugs **94** from moving proximally past them. Accordingly, the stops **96** limit the proximal movement of the slugs **94** and anchor the proximal ends of the tensile fibers **42***b* to effectuate deflection when each is drawn proximally by the deflection control assembly **74**. During assembly of the control handle **16**, before the two housing halves **16***a*, **16***b* are joined, the stops **96** are selectively positioned between the racks **92** to achieve a desirable tension in each tensile member. The interlocking teeth **98** of the racks **92** and stops **96** allow for fine adjustments in setting the tension.

The construction and assembly of the deflection control assembly **74** including the deflection arm **75** and a tension adjustment member **101** on the control handle **16** are described as follows. With reference to FIGS. **14** and **14***a*, the rocker member **78** of the assembly **74** is situated between the two halves **16***a* and **16***b* of the control handle **16**, with each of its annular formations **140***a* and **140***b* extending respectively through an opening **120***a*, **120***b* formed in the distal portion **114** of each housing half **16***a* and **16***b*.

The annular formation **140***a* has recesses **160** (FIG. **10**) exposed through the opening **120***a* (FIG. **15**) that receive protrusions **152** projecting from a facing surface **154** of the deflection arm **75** (FIG. **16**) to rotationally couple the deflection arm **75** and the rocker member **78**. The protrusions **152** can snap fit into the recesses **160** and/or be secured by adhesives, glue, sonic welding and the like. A central circular protrusion **156** from the deflection arm **75** fits into the hole **143** circumscribed by the annular formation **140***a* of the rocker member **78**. A suitable deflection assembly and control handle are described in co-pending U.S. application Ser. No. 12/346,834, filed Dec. 30, 2008, entitled DEFLECTABLE SHEATH INTRODUCER, the entire disclosure of which is hereby incorporated by reference. Another suitable deflection assembly with deflection sensitivity is described in co-pending U.S. application Ser. No. 12/211,728, filed Sep. 16, 2008, entitled CATHETER WITH ADJUSTABLE DEFLECTION SENSITIVITY, the entire disclosure of which is hereby incorporated by reference. Therein, a cam that is responsive to a deflection sensitivity knob can vary the separation distance between the two pulleys **147**, thereby changing the deflection sensitivity of the deflection arm.

Opposing the deflection arm **75** is the deflection tension adjustment member or dial **101** (FIGS. **17** and **20**) which is coupled to and indirectly engaged with the rocker member **78** by various mechanisms and parts and allows an operator to adjust the ease with which the deflection arm **75** can be rotated. Mounted primarily on the housing half **16***b*, the illustrated embodiment of a tension adjustment assembly **100** includes the adjustment dial **101** (FIG. **17**), a locking plate **102** (FIG. **18**), a tension cap screw **103**, a retaining nut **136** and a washer **119** (see FIGS. **14** and **14***a*). A user rotates the dial **101** to adjust the tightness or tension of the rotational movement of deflection arm **75** by effectively compressing or releasing the rocker member **78** against the washer **119** (e.g., a Belleville type) and the control handle housing half **16***b*.

The dial **101** has a generally circular cross section with a circumferential edge **115** having a friction-inducing surface (FIG. **17**). A central circular protrusion **105** and a plurality of prongs **106** (FIG. **17**) situated along a diameter of the dial project from a surface **104** of the dial **101**.

The locking plate **102** is sandwiched between the dial **101** and the handle housing **16***b* (FIG. **20**). The locking plate **102** (FIG. **18**) has a central larger hole **107** and two smaller holes **108**, all three of which extend through the entire thickness of the locking plate. The two prongs **106** of the dial **101** are adapted to be inserted through the smaller holes **108** in the plate **102** (FIG. **21**) and received in semi-circular grooves **109** (FIG. **19**) formed in an outer surface of the housing half **16***b*. The grooves **109** limit the degree of rotation of the dial **101** in clockwise and counterclockwise directions. The central hole **107** of the plate **102** (FIG. **18**) has different cross-sections that include a larger circular cross-section **107***a* and a smaller circular cross-section **107***b*. The larger circular cross-section **107***a* receives a head **112** of a cap screw **103**, and the smaller circular cross-section **107***b* receives a threaded body **115** of the cap screw **103** (FIG. **14***a*).

The threaded body **115** of the cap screw **103** extending through the central hole **107** of the locking plate **102** engages the retaining nut **136** situated in the opening **143** of the rocker member **78**. A head **115** of the nut abuts and is anchored against a neck **132** formed in the inner surface of the opening **143** of the rocker member **78**. The opening **120***b* in the housing half **16***b* (FIG. **21**) has a larger cross section **122** and a smaller cross section **124**. The smaller cross section **124** has a polygonal shape which matches a polygonal (e.g., hexagonal) end **126** of the nut **136** so that the nut **136** is effectively locked against rotation relative to the housing handle **16***b*.

The central protrusion **105** of the dial **101** (FIG. **17**) forms a press or interference fit with the head **112** of the cap screw **103** to create rotational alignment between these two components. The prongs **106** of the dial **101** lock and rotationally couple the dial **101** and the lock plate **102**, and the cap screw **103** is rotationally coupled to the locking plate **102**. Coupling of the dial **101** and the locking plate **102** may also be achieved by means of welding the two components together. In that case, the prongs **106** need not protrude from the dial **101** but can instead extend from the locking plate **102**.

Between the polygonal end **126** of the nut **136** and the housing handle **16***b* is the washer **119** whose compression against the nut **136** and the housing handle **16***b* is adjustable by the user's rotation of the dial **101** which tightens or releases the engagement between cap screw **103** and the nut **136**, thus increasing or decreasing the ease with which the rocker member **78** and hence the deflection arm **75** can be rotated.

Components that extend through the control handle, including, for example, the lead wires **40** and the contraction wire **35** also enter the control handle at the distal end. In the illustrated embodiment of FIG. **9**, these components extend along the longitudinal axis of the control handle. A protective tubing **152** through which the components extend can be provided, positioned between the two deflection puller members **42** and through a channel **150** form through the width dimension W of the rocker member **78** (FIG. **11**). Distal and proximal portions of the channel **150** have indents, e.g., triangular or wedge-shaped, **151** (FIGS. **9** and **11**) to allow the rocker member **78** to rotate freely within a predetermined range of angles, e.g., about ±45 degrees of the longitudinal axis of the control handle **16**, without interference by the tubing **152** and the components therethrough.

Alternatively, the components extending through the control handle, with the exception of the contraction wire **35**, are routed on an off-axis path **153** diverging from the deflection puller members **42** at entry into the distal end of the control handle **16**. The components thus extend along the periphery of the housing handle, bypassing the rocker member **78**.

It is understood that the distance between the distal end of the compression coils **44** and the distal anchor sites of each deflection puller members **42** in the intermediate section **14** determines the curvature of the intermediate section **14** in the direction of the deflection puller members. For example, an arrangement wherein the two deflection puller members **42** are anchored at different distances from the distal ends of the compression coils **44** allows a long reach curve in a first plane and a short reach curve in a plane 90.degree. from the first, i.e., a first curve in one plane generally along the axis of the intermediate section **14** before it is deflected and a second curve distal to the first curve in a plane transverse, and preferably normal to the first plane. The high torque characteristic of the catheter intermediate section **14** reduces the tendency for the deflection in one direction to deform the deflection in the other direction. Suitable deflection control handles and parts thereof for use with such a catheter are described in U.S. patent application Ser. No. 08/924,611, filed Sep. 5, 1997, entitled "Omni-Directional Steerable Catheter", Ser. No. 09/130,359, filed Aug. 7, 1998, entitled "Bi-Directional Control Handle for Steerable Catheter", and Ser. No. 09/143,426, filed Aug. 28, 1998, entitled "Bidirectional Steerable Catheter with Bidirectional Control Handle", the entire disclosures of which are hereby incorporated by reference.

For adjusting the mapping assembly **17** by means of a third puller member, e.g., the contraction wire **35**, a distal end of the contraction wire extending between the two deflection puller members **42** within the control handle is anchored in the control handle for actuation by means of a rotational control assembly **200**. In the illustrated embodiment of FIG. **23**, the rotational control assembly **200** includes an outer rotational cam **202**, a pulley shaft **204** and a pulley **206** around which the third puller member **35** is wrapped. The cam **202** closely surrounds the proximal portion **116** of the control handle and as the proximal portion **116** has a cylindrical shape, the rotational cam is in a circumferential relationship with the proximal portion so that it can rotate about a longitudinal central axis **205** of the proximal portion **116** on an outer surface **208** of the proximal portion and serve as a rotational interface between the user and internal components of the rotational control assembly **200**. In that regard, the outer surface **208** is sufficiently smooth such that the cam **202** can rotate on it with minimal frictional forces. A friction-inducing surface can be provided on an outer surface of the cam **202** to facilitate manipulation and rotation by the user.

The proximal portion **116** under the cam **202** has two diametrically opposing guide slots **208** extending axially in a direction parallel to the longitudinal axis **205** of the proximal portion **116**. The cam **202** has on its inner surface two opposing helical tracks or grooves **210** extending about the longitudinal axis **205**. The helical grooves **210** are configured such that any plane perpendicular to the longitudinal axis intersects the grooves along a diameter of the proximal portion **116**. The shaft **204** extends diametrically between the two guide slots **208**, traversing the interior of the proximal portion at an angle generally perpendicular to the longitudinal axis **205**. The guide slots **208** are sized so that the shaft **204** can pass through the slots and have each of its two opposing ends **212** be received in a respective helical groove on the inner surface of the cam. As such, the length of the shaft is greater than an outer diameter of the proximal portion **116** but lesser than an outer diameter of the cam **202**. Accordingly, the helical grooves **210** are sized to receive the ends **212** and allow the ends to slide therein.

Mounted on the shaft, for example, at or near a midpoint of the length of the shaft, is the pulley **206** on which the third puller member is wrapped. The third puller member which can be any suitable material, including a puller wire or contraction wire, has a proximal end (not shown) that is anchored to the control handle or to any other rigidly mounted component within the control handle, at a location distal of the distal ends of the guide slots. Longitudinal movement of the contraction wire **35** relative to the catheter body **12** can effectuate, for example, contraction and expansion of the mapping assembly **17**.

With reference to embodiment of FIGS. **1**, **23** and **24**, the rotational control assembly **200** is positioned proximal the deflection control assembly **74**, although it is understood that it can be positioned distal the deflection control assembly **74**. In the disclosed embodiment, the cam **202** is mounted on the proximal portion **116** of the control handle. The cam **202** can be formed from as a solid piece that slides onto the proximal portion and is snap-fitted over the two ends **212** of the shaft **204**. Alternatively, the cam can be formed of two halves that are snap-fit to each other or joined by glue or sonic welding over the two ends of the shaft.

In operation, the rotational control assembly **200** is manipulated by means of the cam **202**. As a user holds the control handle **16** and rotates the cam with his thumb and forefinger to contract or expand the mapping assembly, the two opposing helical tracks **210** on the inner surface are rotated relative to the proximal portion **116** thereby exerting a force on the shaft **204** via the ends **212** received in the tracks **210** to diametrically spin about the central longitudinal axis **205** of the control handle. However, because the shaft **204** extends through the guide slots **208** of the proximal portion **116**, the guide slots limit the shaft to a translational movement proximally or distally along the longitudinal axis depending on the direction of rotation of the cam **202** as the ends **212** slide in the helical tracks **210**. As the shaft **204** moves proximally or distally, the pulley **206** thereon correspondingly moves proximally or distally thereby drawing or releasing the third puller member **35**. Advantageously, the rotational control assembly provides a multiplied linear motion of the third puller member, with greater sensitivity in the amount of motion controlled by the user. In the disclosed embodiment of FIG. **24**, each helix **210** has a rotation of about 540° (360'+180°). However, it is understood that the rotation of each helix can range between about 180° to 720° depending on how much contraction/deflection and/or how much sensitivity is desired.

Lead wires and other components (e.g., thermocouple wires, cables, irrigation tubing) extending through proximal portion **116** in a protective tubing so as not to interfere with the interior components of the rotational control assembly.

In use, a suitable guiding sheath is inserted into the patient with its distal end positioned at a desired mapping location. An example of a suitable guiding sheath for use in connection with the present invention is the Preface™. Braiding Guiding Sheath, commercially available from Biosense Webster, Inc. (Diamond Bar, Calif.). The distal end of the sheath is guided into one of the chamber, for example, the atria. A catheter in accordance with the present invention is fed through the guiding sheath until its distal end extends out of the distal end of the guiding sheath. As the catheter is fed through the guiding sheath, the mapping assembly **17** is straightened to fit through the sheath. Once the distal end of the catheter is positioned at the desired mapping location, the guiding sheath is pulled proximally, allowing the deflectable intermediate section **14** and mapping assembly **17** to extend outside the sheath, and the mapping assembly **17** returns to its original shape due to the shape-memory of the support member **54**.

By manipulating and rotating the deflection arm **75** of the deflection control assembly **74** to deflect the intermediate section **14**, the mapping assembly **17** is then inserted into a pulmonary vein or other tubular region (such as the superior vena cava, or inferior vena cava) so that the outer circumference of the generally circular main region **39** of the assembly **17** is in contact with a circumference inside the tubular region. Turning the deflection arm **75** in one direction deflects the intermediate section **14** to that direction. Turning the deflection **75** in the opposite direction deflects the intermediate section **14** to that opposite direction. Tension of the deflection **75** is adjusted by manipulating and rotating the dial **101**. Turning the dial **101** in one direction increases the tension. Turning the dial **101** in the opposition direction decreases the tension. Preferably at least about 50%, more preferably at least about 70%, and still more preferably at least about 80% of the circumference of the generally circular main region is in contact with a circumference inside the tubular region.

The circular arrangement of the electrodes **26** permits measurement of the electrical activity at that circumference of the tubular structure so that ectopic beats between the electrodes can be identified. The size of the generally circular main region **39** permits measurement of electrical activity along a diameter of a pulmonary vein or other tubular structure of or near the heart because the circular main region has a diameter generally corresponding to that of a pulmonary vein or the coronary sinus. By manipulating and rotating the cam **202** of the rotational assembly **200**, the assembly **17**, in particular, the generally circular main region **39**, is contracted to fit the pulmonary vein or other tubular structure.

In accordance with a feature of the present invention, rotational motion of the cam results in linear motion of the shaft and the pulley along the central longitudinal axis of the control handle. The shaft rides along the helical grooves of the cam as it is rotated. The opposing linear guide slots of the proximal portion of the control handle ensure that the shaft maintains its general perpendicular orientation resulting in linear motion of the shaft relative to the proximal portion. As the shaft translates along the longitudinal axis, the pulley is also moved wherein its linear displacement results in twice the linear displacement of the third puller member. In the disclosed embodiment, the contraction wire is drawn proximally by the rotational control assembly to tighten and decrease the diameter of the generally circular region **39** when the cam is turned in one direction. By turning the cam in the opposition direction, the contraction wire **35** is released to release the generally circular region **39** such that it expands its diameter.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. It is understood that the present invention is applicable to multiplying linear motion of a puller wire, contraction wire, or any other object requiring insertion, removal, or tensioning within a medical device, including the disclosed electrophysiology catheter. As understood by one of ordinary skill in the art, the drawings are not necessarily to scale. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

What is claimed is:

1. A catheter comprising:

a catheter body;

a deflectable intermediate section distal the catheter body;

a mapping assembly distal the intermediate section, the mapping assembly having a distal configuration;

a control handle proximal the catheter body, the control handle having:

a deflection control assembly; and

a rotational control assembly comprising a rotational cam, a shaft, and a pulley, the rotational cam being in a circumferential relationship with a portion of the control handle and adapted for rotation about a longitudinal axis of the control handle, the rotational cam having an inner surface with two opposing helical tracks, the portion of the control handle having two opposing guide slots extending in parallel with the longitudinal axis, the shaft extending along a diameter of the portion of the control handle generally perpendicular to the longitudinal axis of the control handle, the shaft having two opposing ends, each of which extends through a respective guide slot in the portion of the control handle and is received in a respective helical track in the rotational cam, the pulley being mounted on the shaft;

one or more deflection puller members responsive to the deflection control assembly adapted to deflect the intermediate section; and

a contraction puller member responsive to the rotational control assembly adapted to contract the distal configuration of the mapping assembly.

2. A catheter of claim **1**, wherein a proximal end of the contraction puller member is anchored inside the control handle at a location distal of the shaft.

3. A catheter of claim **1**, wherein the rotational cam is outside of the portion of the control handle with which it is in a circumferential relationship.

4. A catheter of claim **1**, wherein the distal configuration is contracted when the user rotates the rotational cam.

5. A catheter of claim **1**, wherein the distal configuration is expanded when the user rotates the rotational cam.

6. A catheter of claim **1**, wherein the shaft rotates about its longitudinal axis and translates along the longitudinal axis of the control handle while remaining generally perpendicular thereto when actuated by the rotational cam.

7. A catheter of claim **1**, wherein rotation of the rotational cam in one direction expands the distal configuration and rotation of the cam in an opposite direction contracts the distal configuration.

8. A catheter of claim **1**, wherein the ends of the shaft ride along the helical tracks as the rotational cam is rotated.

9. A catheter of claim **1**, wherein the shaft remains generally perpendicular to the longitudinal axis of the control handle as the rotational cam is rotated.

10. A catheter of claim **1**, wherein the shaft moves within the linear guide slots as the rotational cam is rotated.

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